Exhibit D

insight
exposure & risk sciences group

August 14, 2020

Daniel Adams
Larson King, LLP
30 East Seventh Street
St. Paul, Minnesota 55101

Subject: Expert Report in the matter of *James LaFrentz and Ila LaFrentz v. 3M Company, et al. (regarding 3M Company)*

Dear Mr. Adams:

I have prepared the attached report in response to the request for my retention in the James LaFrentz matter made on August 5, 2020. The first set of case materials was received for my review on August 5, 2020.

It is my understanding that I have been retained by counsel on behalf of 3M to offer my opinions concerning the regulatory standards and requirements over time related to respirator use, as well as respirator use with asbestos, employer responsibility, Mr. LaFrentz's asbestos exposure potential, and the historical evolution of knowledge of industrial hygienists regarding asbestos.

My opinions are reflected in the attached report. I have also provided a brief description of my background and areas of expertise relating to this matter, including a discussion of my knowledge and experience in the field of industrial hygiene.

Respectfully,

Jennifer Sahmel, MPH, CIH, CSP, FAIHA
Managing Principal Scientist

Attachments

Expert Report of
Jennifer Sahmel, MPH, CIH, CSP, FAIHA

Expert Report in the matter of *James LaFrentz and Ila LaFrentz v. 3M Company, et al. (regarding 3M Company)*

Prepared for:

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August 14, 2020

I. EXPERIENCE

I am a Certified Industrial Hygienist (CIH) [American Board of Industrial Hygiene (ABIH)] and a Certified Safety Professional (CSP) [Board of Certified Safety Professionals (BCSP)] with over 23 years of experience in human health exposure, risk assessment, and workplace health and safety. I am also a Fellow of the American Industrial Hygiene Association (FAIHA) and a Research Fellow of the Exposure Science and Sustainability Institute at the University of Minnesota. I have experience in exposure assessment methodologies, the history and state of the science for industrial hygiene over time, health risk decision making, exposure monitoring, and safety management systems. I have conducted chemical-specific exposure assessments for a wide range of substances, including asbestos, acrylamide, benzene, carbon monoxide, silica, diesel exhaust, solvents, vinyl chloride, phthalates, talc, lead, and cadmium.

In my current position, I am a Managing Principal Scientist of Insight Exposure and Risk Sciences. Insight is dedicated to addressing scientifically complex and technical questions related to human health and safety, including exposure and risk assessment. I specialize in the disciplines of industrial hygiene, exposure science, occupational and consumer exposure assessment, and exposure reconstruction. This includes but is not limited to dermal, inhalation, and ingestion exposure potential to agents found in consumer products, the ambient air, industrial materials and other media.

My publications include a comprehensive review paper on exposure reconstruction methods for human health risk assessment (Sahmel et al. 2010), as well as a review of the history and evolution of knowledge of industrial hygienists regarding asbestos (Barlow et al. 2017). I have specifically published on the topics of asbestos bystander and take home exposure potential, fiber settling, and the epidemiology of background exposures (Donovan et al. 2011; Sahmel et al. 2014a; Sahmel et al. 2016; Sahmel et al. 2015a; Glynn et al. 2018). I have also published papers addressing the use of industrial hygiene principles, exposure assessment, and exposure reconstruction for vinyl chloride, benzene, carbon monoxide, talc, lead, and a number of other chemicals (Paustenbach et al. 2010; Sahmel et al. 2009b; Williams et al. 2011; Sahmel et al. 2014b; Sahmel et al. 2015c; Avens et al. 2018; Burns et al. 2019).

I am active in the industrial hygiene scientific community in the United States and internationally, and have served on both International Standards Organization (ISO) and American National Standards Institute (ANSI) committees, including the ANSI Z88 Committee between 2000 and 2017. I was elected to the American Industrial Hygiene Association's (AIHA's) Board of Directors

for 2014-2017. I am also a past Chair of the AIHA's Exposure Assessment Strategies Committee, and the founder of the committee's working group on dermal exposure assessment. I am a co-author for the committee's text on exposure assessment strategies (Ignacio et al. 2006; Sahmel et al. 2006a; Sahmel et al. 2006b; Sahmel et al. 2015b; Boeniger et al. 2015) and the committee's occupational exposure mathematical modeling textbook (Keil et al. 2009; Sahmel et al. 2009a). Additionally, I have been an instructor for multiple professional development courses on exposure assessment for the AIHA's annual conference (AIHCE) for the past nine years, including the topics of exposure assessment strategies, exposure assessment modeling, dermal exposure assessment, and professional judgment in exposure assessment. I was also an instructor for the committee's Exposure Assessment Symposia in 2003, 2005, and 2009.

I have been invited to give presentations and workshops on exposure assessment at NASA's annual Occupational Health Conference, the Navy and Marine Corps Public Health Conference, the China-U.S. Occupational Health Symposium, the National Institute for Occupational Safety and Health, the Colombian Society for Occupational Hygiene, the California Industrial Hygiene Council (CIHC), and multiple local geographic chapters of the AIHA. I am a current Co-Chair of the NIOSH-facilitated National Occupational Research Agenda (NORA) Cross-Sector Council for Immune, Infectious, and Dermal Disease. NORA is a partnership program to stimulate innovative research and improved workplace practices, in which diverse parties collaborate to identify the most critical issues in workplace safety and health and then make progress on those issues through information sharing, collaboration, and enhancing dissemination and implementation of evidence-based practices. I was also a member of the NIOSH Expert Workgroup on Skin Notations and Dermal Exposure Issues (2005-2009), which was charged with assisting the agency in updating and expanding the NIOSH skin notations and provided expert guidance to NIOSH on dermal exposure issues.

While working in the U.S. EPA's Office of Pollution Prevention and Toxics (OPPT) in their Chemical Engineering Branch, I reviewed and contributed to occupational health and exposure assessment research and standards for the management of numerous national programs including the Toxics Substances Control Act, the Pollution Prevention program, Green Engineering, Design for the Environment, National Program Chemicals, Voluntary Children's Chemical Evaluation Program (VCCEP), and counter-terrorism activities. I worked with numerous EPA risk assessment models to evaluate a wide variety of exposure scenarios.

My professional education, training, and background are consistent with the topics and areas of scientific study about which I will testify. My curriculum vitae, which presents my background and training, is included as Attachment A to this report.

II. MATERIALS REVIEWED IN FORMULATING OPINIONS

My opinions are based on my professional qualifications, work experiences, and knowledge of industrial hygiene, exposure assessment, and related fields. My views are also based on information that is related to this case. In the process of preparing this report, I have received the following case-specific documents:

1. Plaintiffs' Second Amended Complaint
2. Deposition transcript of James LaFrentz, dated November 14, 2018
3. Deposition transcript of James LaFrentz, dated November 15, 2018
    a. Exhibits to the depositions of James LaFrentz
4. Plaintiffs' Third Supplemental Rule 26(A) Disclosure
5. Expert Report of Darell Bevis
6. Expert Report of Ken Garza

I have also reviewed and relied upon published papers, reports, regulatory materials and textbooks on industrial hygiene, toxicology, medicine, and standard practices associated with asbestos use available in the open literature. Specific references cited in my opinions are listed at the end of this report.

My opinions and the basis for these opinions are provided in Sections IV and V of this report. I express these to a reasonable degree of scientific certainty. It is my understanding that discovery is ongoing in this matter, and therefore I reserve the right to supplement this report in the event that additional information becomes available. My time spent in the preparation of this opinion letter and reviewing documents to formulate my opinions as well as for any deposition or trial testimony I may be called upon to give will be billed at a rate of $395 per hour.

III. CASE-SPECIFIC INFORMATION

General Case Summary

Mr. James Benjamin LaFrentz was born on November 24, 1944, and was reportedly diagnosed with mesothelioma in June 2018, at the age of 73 (LaFrentz Vol. I: p. 24). He reported that he had previously been diagnosed with kidney cancer in 1994 (LaFrentz Vol. 2: p. 11). He testified that he began smoking when he was 15 or 16, and recalled smoking "mainly Marlboro" brand cigarettes (LaFrentz Vol. I: p. 146, l. 18). He indicated that he smoked one or two cigarettes per day in high school, and then as an adult smoked "maybe a pack a day" of Marlboro Reds or Marlboro Lights; he never recalled smoking Kent cigarettes (LaFrentz Vol. I: p. 147, l. 21; p. 148).

Mr. LaFrentz testified that he was a member of the International Association of Machinist and Aerospace Workers while employed as a machinist at General Dynamics (LaFrentz Vol. I: p. 165). He also believed that he "had to be a member of some kind of steamfitters union while [he] worked" one summer as an apprentice (LaFrentz Vol. I: p. 166). He did not recall ever receiving any education or warnings from the steamfitters union regarding the hazards of asbestos (LaFrentz Vol. I: p. 175).

Mr. LaFrentz was not aware of any claims that had been submitted to bankruptcy trusts (LaFrentz Vol. I: p. 192-193).

Summer Employment During High School (summers from 1960 or 1961 to 1963)

Mr. LaFrentz testified that he worked in the summers during high school in Austin, Texas, and stated that before 1963, he "cleaned up construction sites" on commercial jobs including "sheetrock and lumber and trash" and indicated that he "was the clean-up kid" (LaFrentz Vol. I: p. 35, l. 24; p. 36, l. 19, 22; p. 37). He believed that the project involved remodeling rather than new construction (LaFrentz Vol. I: p. 37). He did not know if he was exposed to asbestos during this work (LaFrentz Vol. I: p. 37-38).

He also recalled that "one year [he] worked as an apprentice steamfitter" and believed that this was the following summer after the construction site job (LaFrentz Vol. I: p. 35, l. 24-25; p. 36, l. 1-2; p. 38). During this employment, he stated that he "helped one guy" and recalled that they were "redoing piping in the basement of an unoccupied hospital" (LaFrentz Vol. I: p. 38, l. 9-10). He indicated that the work he did was consistent with an apprentice, and that he would "put

goop on pipes and [screw] them in and all the old pipes out" (LaFrentz Vol. I: p. 38, l. 20-21). He did not recall if they took any insulation off of the piping systems they removed (LaFrentz Vol. I: p. 168). He agreed that "the whole area was always dusty" (LaFrentz Vol. I: p. 170). He did not recall whether he wore any type of dust mast while performing this work (LaFrentz Vol. I: p. 170).

He testified that he worked "one year [he] worked with the Texas Highway Department on the road crew" (LaFrentz Vol. I: p. 36, l. 1-2). He recalled that they "threw out and patched highways with asphalt" and "cleaned brush, picked up trash" (LaFrentz Vol. I: p. 39, l. 14-15).

Army Reserves/National Guard/Texas National Guard/Air Force Reserves (November or December 1964 to 1978)

Mr. LaFrentz testified that he was drafted in 1964 and reported to the Army National Guard in Camp Mabry in Austin, Texas (LaFrentz Vol. I: p. 40). He was later sent to Fort Bragg, North Carolina, and then Fort Lee, Virginia (LaFrentz Vol. I: p. 49). Following basic training, he recalled that he was in the reserves in the Texas National Guard and served in a "quartermaster's unit" which was "dealing with food and rations" (LaFrentz Vol. I: p. 50, l. 14, 17). He later became a helicopter mechanic and worked at Camp Mabry and Bergstrom Air Force Base or the Austin City Airport (LaFrentz Vol. I: p. 51). He also recalled working as the supervisor of a construction unit at La Crosse, Wisconsin, during his first year in Ohio (LaFrentz Vol. I: p. 52).

After moving back to Texas in 1978, Mr. LaFrentz stated that he joined the Air Force Reserves, and served in the reserves until 1991 (LaFrentz Vol. I: p. 52). He recalled that for the first two years, he was a machinist, and subsequently transferred and was accepted into intelligence; he stated that he then finished the last ten years of his service in the Air Force Intelligence, which involved providing intelligence briefings to flight crews (LaFrentz Vol. I: p. 53). Mr. LaFrentz testified that while he was working as a machinist in the reserves at Carswell Air Force Base, he "ran a lathe" and would get "called on to go out and take screws out of the panels in the aircraft" when they were "buggered up"; he described that they would take the old screws out and put new screws in (LaFrentz Vol. I: p. 163, l. 21-23; p. 164).

While working in intelligence, he testified that he would go "two, three weeks two or three times a year to some kind of an exercise. Turkey, Greece, Germany"; he recalled that he went to Incirlik, Turkey (LaFrentz Vol. I: p 160, l. 4-6).

Stereo Installation (1964-1970)

Mr. LaFrentz reported that he had a job installing "two-way radio systems in the trucks of the district supervisors" at the Texas Highway Department (LaFrentz Vol. I: p. 44, l. 12-13). He also recalled that he "installed eight-track stereos in cars" from approximately 1967 to 1970 for "a couple of years" (LaFrentz Vol. I: p. 41, l. 12-13, 24; p. 42).

Farming (Father-in-Law's Farm) (approximately 1970 or 1971 to 1978)

Mr. LaFrentz testified that he and his wife moved to Ohio for approximately five years after his father in law was injured to help him with his farm (LaFrentz Vol. I: p. 43-45).

Mobile Home Construction (1970-1971)

Mr. LaFrentz testified that he got a job in Bryan, Ohio, for approximately "a year and a half, two years" in which he was "working at a mobile home company the built mobile homes from... scratch" (LaFrentz Vol. I: p. 45, l. 19-20). He recalled that he did "plumbing, ran waterlines, helped with drywall... cleaned up the area" (LaFrentz Vol. I: p. 46, l. 2-3). He believed that he was present when they put insulation in the walls (LaFrentz Vol. 2: p. 144).

Aero (1971 or 1972-1978)

Mr. LaFrentz testified that he worked for the Aero Corporation from approximately 1971 or 1972 to 1978 as a machinist (LaFrentz Vol. I: p. 47). He recalled that he "ran a mill, a lathe" in the machine shop and did not typically visit other areas of the facility (LaFrentz Vol. I: p. 47, l. 10, p. 48). He described that the products being manufactured were "precision air tools" that were "used in surgery" (LaFrentz Vol. I: p. 47, l. 15, 18).

Machine and Lathe Operation (1978)

Mr. LaFrentz recalled that he moved back to Texas in 1978, and worked for a company for about a year where he was a "lathe operator" involving "big round blocks of metal" (LaFrentz Vol. I: p. 48, l. 13-14).

General Dynamics Corporation/Lockheed Martin (1979 – 2005)

Mr. LaFrentz testified that he went to work for General Dynamics at Carswell Air Force Base in Fort Worth, Texas, in 1978 or January 1979 (LaFrentz Vol. I: p. 55-56, 121-122). He recalled that the facility was building F-16 aircraft as well as some F-111 aircraft for the U.S. Air Force (LaFrentz Vol. I: p. 56-58). He believed that the aircraft built at the facility were built in accordance with U.S. Government military specifications (LaFrentz Vol. I: p. 126). He agreed that the facility where he worked was known as Air Force Plant Number 4, and was approximately a mile long, and he described that the building had "more or less two stories" to "facilitate the overhead crane" and that the building was 100 to 150 feet high (LaFrentz Vol. I: p. 114-115, Vol. 2: p. 149). He believed that the parts fab area where he specifically worked was "maybe 200 foot by 200 foot" (LaFrentz Vol. 2: p. 150).

He stated that he started as a drill press operator in the "parts fab department" with 30 to 40 other workers, and believed that he worked in this department for "probably a little over three years" from approximately 1979 to 1981 or 1982 (LaFrentz Vol. I: p. 58, l. 9, p. 59, l. 7, p. 87, 129; Vol. 2: p. 147). As part of this job he recalled that his duties included "basically anything that needed to be drilled, [he] would drill it. [He] drilled speed brakes out of raw aluminum. [He] drilled coupons for testing" and generally "drilled mostly anything" (LaFrentz Vol. I: p. 59, l. 15-18; Vol. 2: p. 152-153). He also recalled drilling some brass parts and some steel (LaFrentz Vol. 2: p. 153). He recalled using a half-inch drill bit (LaFrentz Vol. 2: p. 158). He described that a "coupon" was "the honeycomb" and "came in three different varieties" (LaFrentz Vol. I: p. 59, l. 25; p. 60, l. 1). Regarding the coupon or honeycomb, he indicated that "one was a panel and one was a strip" and that "the panels were composite material on top of a metal plate" (LaFrentz Vol. I: p. 60, l. 3-4). He later agreed that there were three different types of coupons: honeycomb, panel, and strip, but also agreed that coupon and honeycomb were the same (LaFrentz Vol. I: p. 131). Later still, he testified that Honeycomb, panel, and strip were different shapes (LaFrentz Vol. 2: p. 113). He stated that he "dealt with a honeycomb-type of a panel", and that he also "dealt with a panel that had metal base on it" and that he "dealt with a strip of that panel (LaFrentz Vol. 2: p. 114, l. 21-23; Vol. 2: p. 164). He agreed that there was a document produced as an exhibit that addressed the use of adhesive in the panels (LaFrentz Vol. 2: p. 162).

Mr. LaFrentz described a honeycomb panel as a "quarter inch of material across the top and then a wafered-type center and then this panel or this same type of composite material on the bottom"; he recalled that the dimensions of most of the honeycomb panels he worked on were "eight by ten by inch and a half, inch and a quarter thickness for the panel" (LaFrentz Vol. I: p.

131, l. 17-20, 23-24). He later estimated the thickness of the panels as approximately 5/16ths of an inch (LaFrentz Vol. I: p. 133). He recalled that the look of the composite material did not change during the approximately three-year period he performed work with the coupons, but he did not know if the chemical composition ever changed (LaFrentz Vol. I: p. 132-133). He testified that the strip coupons he recalled were "probably 11 by one and a half by the thickness" (LaFrentz Vol. I: p. 134, l. 3-4). He recalled that the composite strips were "a yellow-ish color" and had different colors (LaFrentz Vol. 2: p. 120).

He agreed that the coupons were test panels for combat aircraft and later stated that he believed they were used for strength testing (LaFrentz Vol. I: p. 116, 126). He recalled that on the panels, they "drilled the four corners so they could stretch them and see what it took to break them"; he stated that the "strip was ... basically the same thing, but it was just more or less composite-type material" that they "drilled at each end for them to test" (LaFrentz Vol. I: p. 60, l. 5-6, 9-11, 13-14, Vol. 2: p. 115-116). After his work as a drill press operator, Mr. LaFrentz testified that he became an "NC machinist" for approximately two years, and recalled that in this position he worked on "three and a five-axis machine milling and drilling and everything that needed to be done to that particular part" (LaFrentz Vol. I: p. 60, l. 21-23).

Regarding his work with the "coupons" or honeycomb, Mr. LaFrentz testified that "they would bring them out in a plastic bin" and "there may [have been] 20 or 30 or so in that bin" (LaFrentz Vol. I: p. 65, l. 8-9, 11-12). He described that he "might have to do this for two days" and then he "might... not have another bin come out for a month" (LaFrentz Vol. I: p. 65, l. 12-13). He recalled if the coupon was a single strip, he would have "two holes to drill and clean up" and "that would take from start to finish probably 30 to 45 minutes" (LaFrentz Vol. I: p. 65, 66, l. 3-6). He later testified that if it was "a strip panel, it had two holes" and would take "probably 20, maybe 30 minutes at the most" from start to finish to drill, sand, and deburr the panels each time (LaFrentz Vol. 2: p. 168). He further explained that "if it was a panel that was... [a] metal panel that had four holes in it, it would probably take 30, 40 minutes" and finally, "if it was a honeycomb panel, it would take about 15, 20 minutes" (LaFrentz Vol. 2: p. 168, l. 11-17).

He testified that he drilled these panels "off and on" during the three years that he worked as a drill press operator, and did not ever drill them again once he was no longer a drill press operator (LaFrentz Vol. I: p. 66, l. 20). He believed that during this three-year period, he could have drilled "maybe a thousand" of the coupons or panels and stated that he knew "there was quite a few" (LaFrentz Vol. I: p. 67, l. 10, p. 113; Vol. 2: p. 165-166). He later stated that it would take him

"around 15 minutes to 25 minutes" to clean up after he had drilled the panels, or around 30 minutes to an hour to clean his table, fixture, and the floor (LaFrentz Vol. 2: p. 118).

In describing the drilling process of the coupons or panels, he stated that, "if it was a larger panel, which would be something about the size of a piece of paper, it had four holes and it had a fixture" (LaFrentz Vol. I: p. 68, l. 15-17). He agreed that this drilling process would be dusty because he could not use any dust-suppression solution on the panels (LaFrentz Vol. I: p. 69). He also recalled that there was an odor associated with drilling the panels, and it "smelled like something was burning up" (LaFrentz Vol. I: p. 70, l. 7-8). He also described that the drilling process was "always leaving, like, burrs around the hole and the engineers wanted them smooth so they could test them", so he "would have to take and either use the little belt sander we had there to kind of run over it or use the air hand sander" which "had a little disc pad on the end of it" (LaFrentz Vol. I: p. 70, l. 11-17). He also described that he used a "one inch" belt sander and that he would also use an air powered hand drill with a two-inch disc (LaFrentz Vol. 2: p. 117). He further recalled that sometimes he would use a "whirligig" which was "just a little handle that you whipped around inside the hole" (LaFrentz Vol. I: p. 71, l. 19-22). He stated that after he finished drilling the coupon, he would "put that one in the little plastic bin" and "picked up the next one" (LaFrentz Vol. I: p. 73, l. 2-3). He recalled that each little plastic bin held between eight and 14 parts (LaFrentz Vol. 2: p. 118-119). He then recalled that he would clean up (LaFrentz Vol. I: p. 73).

When asked about the process of cleaning up after drilling a bin of coupons, Mr. LaFrentz testified that he would "have to turn around and get ... kind of a desk brush", which he described was a "long-handled brush" to sweep up his desk and the floor; he also believed that sometimes the material "would be stuck in the fixture" so he would have to "get the air hose out and blow the air hose over the fixture to clean it up" and recalled that this process would be dusty (LaFrentz Vol. I: p. 88, l. 13-20).

Mr. LaFrentz believed that he was exposed to asbestos during his work at General Dynamics because of documentation related to air monitoring that was performed in his "work area" (LaFrentz Vol. I: p. 64, l. 3; LaFrentz Exhibit Plaintiff 2).

Following Mr. LaFrentz's work in machining, he testified that he "moved into special program security" and that in this position, he "worked in programs that had to be cleared by the government, and basically kept all of the documentation, the facilities, and the access list secured" (LaFrentz Vol. I: p. 61, l. 8-11).

- Workplace Air Sampling

Mr. LaFrentz reported that he complained to his management regarding the conditions of his work, and called the "safety engineer" about it (LaFrentz Vol. I: p. 82, 83, l. 5). He recalled that her name was B.J. Hallstein, and that when he contacted her, she set up a time to "[test] the air while [he] was drilling" (LaFrentz Vol. I: p. 84). He stated that he gave her a copy of the results in a "little document" that he kept until the time of his deposition; he did not recall the working conditions of his job changing after receiving the results (LaFrentz Vol. I: p. 84, l. 10, p. 85). He indicated that the report stated the contaminant being evaluated was "asbestos" and that there was a concentration of "28.8 fibers per centimeter" (LaFrentz Vol. I: p. 91, l. 8-9). He recalled that he was working on a strip with two holes at the time of the air sampling (LaFrentz Vol. 2: p. 121).

He stated that Ms. Hallstein had "no comment about" whether it was safe or not safe to be drilling and sanding the coupons, and provided "no instructions" regarding whether to continue wearing the same respiratory protection; he did not recall anyone telling him to change his work practices after the air sampling that was performed (LaFrentz Vol. I: p. 86, l. 2; Vol. 2: p. 159). Mr. LaFrentz testified that he personally became aware of what asbestos was "back in '95, 6, somewhere like that" (LaFrentz Vol. I: p. 93, l. 13-14).

- Respiratory Protection

Mr. LaFrentz testified that during the coupon drilling process, he "had a mask on" which he described as a "dust mask" that he "got from the parts man" (LaFrentz Vol. I: p. 72, l. 7, p. 73). He stated that he was not aware of any policies that required him to use a dust mask while performing the coupon drilling work (LaFrentz Vol. I: p. 74). He did not recall whether he had a dust mask on the very first time he started drilling (LaFrentz Vol. I: p. 74). He stated that he was first prompted to request a dust mask for this work because he was "trying to get away from all the black dust and smell"; he later described a "black fog" (LaFrentz Vol. I: p. 74, l. 25 – p. 75, l. 1; Vol. 2: p. 168). He indicated that he would wear the mask "all the time"(LaFrentz Vol. I: p. 80, l. 17).

Mr. LaFrentz recalled that when he asked for the dust mask, he went to a parts cage about "50 feet or so" from where he was working (LaFrentz Vol. I: p. 77, l. 5). He recalled that they "took a paper mask" out of a "four by four by six cardboard box" and handed it to him (LaFrentz Vol. I: p. 77, l. 25; p. 78, l. 1). He believed that the mask "was a 3M dust protector" and that it "was 8710" (LaFrentz Vol. I: p. 78, l. 4, 7). He recalled that the mask "was kind of whitish-gray with two yellow

bands on it" and had metal across the nose; he did not recall if anything was written on the mask (LaFrentz Vol. I: p. 78, l. 9-10). He reported that he did not have any facial hair during that time or ever (LaFrentz Vol. I: p. 78-79). He believed that he wore the same mask during the three years he was a drill press operator (LaFrentz Vol. I: p. 81). He recalled that "most of the time", he would wear the same mask all day (LaFrentz Vol. I: p. 82, l. 3). He also recalled that "sometimes" he would wear the same respiratory protection once he became a machinist (LaFrentz Vol. I: p. 86, l. 20). He later clarified that it was "probably a week until [he] got the mask" after he started drilling the panels (LaFrentz, Vol. 2: p. 106, l. 8).

Mr. LaFrentz testified that he did not ever see an instruction sheet with the 3M 8710, or any product warnings, literature, brochures, or advertisements (LaFrentz Vol. 2: p. 108).

- Workplace Safety

Mr. LaFrentz testified that while he was working in "parts fab", there was a 30-minute safety meeting every "Monday morning or Friday morning"; he did not recall asbestos or dust being discussed at these meetings (LaFrentz Vol. I: p. 95, l. 4-5). He recalled that he was required to get a physical exam and x-rays before he started working at General Dynamics, but did not require ever doing any x-rays again while he worked there (LaFrentz Vol. I: p. 96). He recalled that he was issued safety goggles, but testified that he was not provided with any type of work uniform (LaFrentz Vol. 2: p. 151). He reported that he would not get an apron "unless [he] knew it was going to be a real dirty job" (LaFrentz Vol. 2: p. 152). He believed that General Dynamics "had a pretty good safety record" (LaFrentz Vol. I: p. 98, l. 7). He indicated that he did not have in his possession any manuals or newsletters from the time of his employment (LaFrentz Vol. I: p. 123).

IV. OVERVIEW OF OPINIONS

1) The 3M respirator model 8710 identified by Mr. LaFrentz was not an asbestos-containing product and did not add to particle or asbestos exposure potential through its use. Respiratory protection can only serve to reduce exposure to airborne contaminants, especially when worn and used in conjunction with a properly administered respiratory protection program as specified by ANSI Z88.2 and OSHA 1910.134.

2) State and Federal guidance, standards, and laws relating to appropriate use of respiratory protection have been in place throughout much of the past century. These standards emphasize the hierarchy of controls and the use of respiratory protection only in certain instances and as a last resort following the implementation of other controls, such as ventilation, engineering controls, and work practice controls.

3) The applicable regulations and standards clearly state the responsibility of employers to implement and maintain an appropriate worker protection program, including a respiratory protection program with the necessary elements as set forth in OSHA Section 1910.134 if respirators will be used in the workplace.

4) According OSHA 1910.93a (1972), the class of respirators which includes the 3M 8710 respirator was approved for use with airborne particulates, including asbestos, and provided protection up to 10 times the OSHA ceiling or 8-hour TWA permissible exposure limit for asbestos when used appropriately within an employer-established respiratory protection program, as required by law.

5) Industrial hygiene knowledge regarding asbestos has evolved through the process of incremental scientific study. From the early 1900s until the late 1960s, industrial hygienists were primarily focused on occupations with very high asbestos exposures, including mining and asbestos textile and products manufacturing. The evaluation of exposure potential to end users of asbestos-containing products was not a focus of industrial hygienists until the mid- to late 1960s through 1970s.

6) According to his testimony, Mr. LaFrentz operated a drill press at General Dynamics Corporation/Lockheed Martin for approximately three years between 1979 and 1981 or 1982. He recalled work with aircraft test panels approximately two days per month during this time period. Based on the peer-reviewed literature and measured airborne fiber

concentrations during belt sanding activities in Mr. LaFrentz's work area during his employment, his cumulative airborne fiber exposure potential during this work would have been well below the cumulative asbestos exposure potential associated with working at the current OSHA PEL for asbestos over 45 years, and also within or below the range of cumulative lifetime ambient or background exposures experienced by anyone in the general U.S. population.

7) Nevertheless, Mr. LaFrentz testified that he always wore a 3M 8710 respirator after an initial short period of time working with the aircraft test panels, which if used appropriately, would have provided protection up to 10 times the OSHA ceiling or 8-hour TWA PEL for asbestos and resulted in an even lower cumulative airborne fiber exposure potential during this work.

8) Mr. LaFrentz described work with and around insulation during his work as a steamfitter apprentice and potentially at other work locations during his career. Based on the published literature, full-shift airborne fiber concentrations during work with asbestos-containing insulation were likely to have been above or well above the current OSHA full-shift exposure limit for asbestos. Depending on the fiber type, the nature and duration of activities, and potentially other factors, Mr. LaFrentz may have experienced additional exposures during his working lifetime. Because discovery in this case is ongoing, I reserve the right to supplement my opinions in this regard if additional information becomes available.

V. BASIS FOR OPINIONS

Background: Asbestos

The term asbestos comes from the Greek word meaning "unquenchable" or "indestructible." The two commercial groups of asbestos minerals are serpentine and amphibole, with only one commercial mineral, chrysotile, in the serpentine group (Virta 2005). The amphibole group, on the other hand, contains several mineral fiber types including both crocidolite and amosite (Virta 2005). Each of these mineral fiber types has a unique chemical composition (Virta 2005).

In 1946, the American Conference of Governmental Industrial Hygienists (ACGIH), a professional organization of industrial hygienists and other occupational and environmental health professionals, disseminated the first set of acceptable occupational exposure limits, referred to at that time as Maximum Allowable Concentrations (MACs), for a number of commonly-used industrial chemicals, including asbestos. The MAC values were later renamed the Threshold Limit Values (TLVs). The TLVs were set using the best available scientific literature of the time, representing the amount of exposure that it was believed a worker could experience for eight hours a day, 40 hours a week, 50 weeks a year, for a working lifetime of 45 years without adverse health effects. ACGIH clarified that the TLVs "should not be regarded as fine lines between safe and dangerous concentrations" (ACGIH 1955: p. 46). The ACGIH believed that for substances thought to pose a chronic health issue, like asbestos, the important occupational exposure limit would be the full-shift time-weighted average (TWA) concentration; this approach meant that a worker could be exposed to concentrations higher than the TWA for limited periods, so long as the average concentration over eight hours remained below the 8-hour TWA (ACGIH 1955). At this time, the ACGIH adopted a value of 5 mppcf as the recommended full-shift daily exposure limit for all mineral types of asbestos based on the Dreessen et al. (1938) study (ACGIH 1968). This TLV for asbestos was based on the experience in the asbestos textile industry and was intended to protect workers from asbestosis. This 8-hour TWA TLV for asbestos remained the acceptable ACGIH exposure limit through the 1950s and up until 1968 (ACGIH 2001).

In 1968, the ACGIH proposed to change their asbestos TLV and recommended a new ceiling limit of 5 mppcf and an 8-hour TWA TLV of 2 mppcf or 12 f/cc for fibers greater than 5 µm in length. Again in 1970, ACGIH proposed to lower the TWA TLV to 5 f/cc for fibers longer than 5 µm in length, and added a short term exposure limit of 10 f/cc, longer than 5 µm in length, as averaged over 15 minutes. ACGIH adopted the lower TWA TLV for asbestos in 1974 at 5 f/cc greater than

5μm in length and included the designation "human carcinogens ... with an assigned TLV" (ACGIH 1974a; 1974b: p. 46).

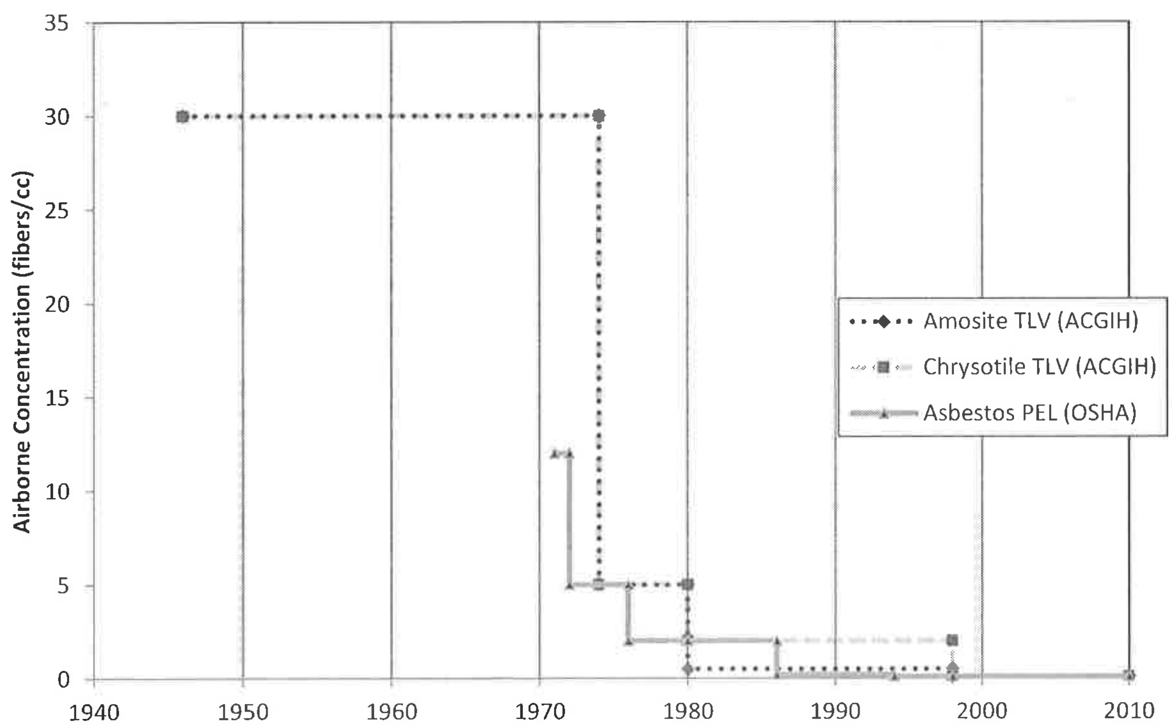
The first U.S. Occupational Safety and Health Act was passed at the end of 1970, and in 1971 the newly formed Occupational Safety and Health Administration (OSHA) promulgated regulatory requirements for the first time for asbestos that were legally binding in a majority of workplaces in the United States. Authorized by Congress under the OSH Act, OSHA adopted the existing Walsh-Healey standards, which included the 12 f/cc or 2 mppcf eight-hour TWA for asbestos, referred to as a Permissible Exposure Limit (PEL) (OSHA 1971b). The PELs for asbestos over time have been based on both an eight-hour TWA using the same methodology established by the ACGIH TLVs as well as 15- or 30-minute short-term TWAs for exposures above the eight-hour TWA. In 1972, OSHA reduced the asbestos PEL to 5 f/cc as an eight-hour TWA, and also stated that "[n]o employee shall be exposed at any time to airborne concentrations of asbestos fibers in excess of 10 fibers, longer than 5 micrometers, per cubic centimeter of air", which was referred to as a 'ceiling concentration'. In subsequent documentation, OSHA clarified that "[a]lthough the existing standard's ceiling limit of 10 f/cc did not include a time period, OSHA had administratively interpreted this provision as prescribing 10 f/cc over a 15 minute period" (OSHA 1986, p. 22682). The 1972 standard included a reduction of the eight-hour TWA PEL to 2 f/cc in 1976 (OSHA 1972b).

In 1983, in conjunction with Dr. William Nicholson of the Environmental Sciences Laboratory of the Mt. Sinai School of Medicine (OSHA Contract #J-94-2-0074) OSHA published a Quantitative Risk Assessment for Asbestos-Related Cancers (OSHA 1983b). In this risk assessment, OSHA used a linear, no-threshold model to estimate the risk for lung cancer and mesothelioma associated with asbestos exposure. For mesothelioma specifically, the agency used exposure information from four studies with high historical exposures to amphiboles or mixed fiber types to extrapolate the risk for disease at lower exposures down to zero (Selikoff et al. 1979; Seidman et al. 1979; Peto 1980; Finkelstein 1983). This model was used by OSHA to determine a value for the updated OSHA 8-hour TWA PEL for asbestos in 1986. In its 1986 standard, OSHA stated that an absolute risk model was used to estimate the risk of mesothelioma in which the "magnitude of the risk increases linearly with intensity of exposure" and "exponentially with duration of exposure and time from onset of exposure" (OSHA 1986, p. 22638). OSHA reported that it used directly-observed risks in worker populations with "past exposures ... higher than those permitted today" in estimating "risk at lower exposure levels" (OSHA 1986, p. 22632). OSHA has continued to use the same risk assessment in subsequent updates to the PELs for asbestos. OSHA lowered the eight-hour TWA PEL to 0.2 f/cc in 1986 and then to the existing level of 0.1 f/cc in 1994; the U.S.

EPA has used the same risk assessment approach for non-occupational scenarios (OSHA 1986; USEPA 1986a; OSHA 1994) (See **Figure 1**). OSHA stated that their 1986 "final standard does not designate a ceiling limit for exposure to asbestos" (OSHA 1986). In 1988, OSHA added an excursion limit of 1 f/cc averaged over a sampling period of 30 minutes (OSHA 1988). In 1990, this excursion limit was also referred to as "a short-term excursion limit (STEL)" (OSHA 1990).

It should also be noted that in 1978, ACGIH recommended that the TLV for asbestos be differentiated by fiber type (ACGIH 1978). According to the ACGIH, different TLVs were warranted based on the weight of available evidence for three different types of asbestos fibers, including crocidolite, amosite, and chrysotile. The recommended TLV for each of these three fibers was 0.2 f/cc, 0.5 f/cc, and 2 f/cc, respectively. The ACGIH stated that "the exposure level of crocidolite and amosite... must be sharply lower than that of chrysotile because of their greater potential for disease production" (ACGIH 1980). In 1997, the ACGIH proposed to lower the eight-hour TWA TLV to 0.1 f/cc for all mineral forms of asbestos and adopted this value in 1998 (ACGIH 1998).

Figure 1: Changes in the Asbestos ACGIH TLVs and OSHA PEL Over Time*



* 5 mppcf was determined to be roughly equivalent to 30 f/cc (Lynch et al. 1968).

Estimating Cumulative Exposure

The exposure assessment process for any substance with the potential for chronic effects, including asbestos, typically includes quantifying to the extent possible the cumulative exposure, or the amount of contact or exposure to the agent of interest over time by all possible routes of entry into the human body. The use of a transparent, step-wise process to assess cumulative exposure is extremely important to produce consistent results from study to study, and is also likely to improve the quality of estimates generated (Sahmel et al. 2010). A number of publications have discussed systematic approaches to the exposure assessment and reconstruction process (Viet et al. 2008; Armstrong et al. 2009; Sahmel et al. 2010; Jahn et al. 2015). The three critical parameters for assessing exposures, and ultimately determining a consistent metric of cumulative exposure, include the duration, frequency, and magnitude or intensity of the exposure. According to the American Industrial Hygiene Association's textbook entitled A Strategy for Assessing and Managing Occupational Exposures, Fourth Ed., sample duration is "one of three important parameters used to describe the extent and potential consequences of exposures; the other two parameters are frequency and magnitude of exposure" (Jahn et al. 2015, p. 537). Similarly, the ATSDR has described that there are a number of factors to consider in determining the potential harm associated with asbestos exposure, including "the dose (how much), the duration (how long), the fiber type (mineral form and size distribution), and how you come in contact with it" (ATSDR 2001, p. 1, 126).

Cumulative Lifetime Exposure – C (f/cc-year)

To estimate cumulative lifetime asbestos exposure potential (C), the following equation can be used (Eq. 1). Each of the parameters in Equation 1 is defined below.

$$C = C_{8hr} \times E_D \qquad \text{(Eq. 1)}$$

Exposure Concentration – C_{8hr} (f/cc as an 8-hour TWA)

The first parameter necessary for estimating exposure potential is the airborne fiber concentration during the work being performed. It is important to use an estimate or calculation of the exposure concentration that characterizes the full work day, or full shift exposure potential, as an 8-hour Time-Weighted Average (TWA). This estimate of full shift exposure potential can represent direct exposures, bystander exposures, or ambient exposures, as examples.

Exposure Duration and Frequency – E_D (years)

The second parameter necessary for estimating exposure potential is the amount or duration of exposure, which encompasses the duration and frequency of exposure over time. For full shift exposure potential, exposure duration can be characterized in terms of days (as a fraction of a year) or years of exposure on either an occupational or environmental year basis. An occupational year consists of 2,080 hours and an environmental year consists of 8,760 hours.

General U.S. Population Ambient/Background Exposures to Asbestos

The U.K. Committee on Carcinogenicity stated that ambient conditions are "the normal conditions surrounding a person," which includes both indoor and outdoor air (Committee on Carcinogenicity 2013, p. 3). Based on its evaluation, the committee reported that the levels of airborne respirable fibers are generally highest in buildings with asbestos that has been disturbed, damaged or is in bad condition, followed by buildings with asbestos in "good condition" and buildings not constructed with asbestos, and are generally lowest in outdoor ambient environments (Committee on Carcinogenicity 2013, p. 12). Based on U.S. EPA data of ambient asbestos levels in buildings with no asbestos-containing material (ACM), buildings with ACM in good condition, and buildings containing damaged ACM, Crump and Farrar (1989) reported similar findings, but found no statistically significant difference in the airborne asbestos levels detected among the three building types (Crump et al. 1989). The Agency for Toxic Substances and Disease Registries (ATSDR) stated in their 2001 Toxicological Profile for Asbestos that the estimated range of indoor ambient concentrations for asbestos is 0.00003 – 0.006 f/cc, which corresponded to cumulative lifetime exposures of 0.002 – 0.4 f/cc-year (ATSDR 2001, p. 151). This range is also consistent with the range of ambient cumulative lifetime exposures for the U.S. population, based on exposure to a combination of indoor and outdoor background asbestos-specific airborne concentration measurements. According to Nolan and Langer (2001), 18.6% of all fibers detected in the indoor and outdoor ambient air were at least 5 µm in length or longer.

Asbestos-specific airborne concentration measurements for fibers of at least 5 µm in length published in the peer-reviewed literature for outdoor ambient or background exposures to asbestos have been reported to be in the range of 0.00003 to 0.0047 f/cc (Nolan et al. 2001; Sahmel et al. 2014a; Lee et al. 2008). Based on these recent data, lifetime cumulative outdoor ambient or background exposures to asbestos experienced by the general U.S. population over 70 years are in the range of 0.0021 to 0.33 f/cc-year (Nolan et al. 2001; Sahmel et al. 2014a; Lee

et al. 2008). Abelmann et al. (2015) conducted a review and analysis of outdoor asbestos air concentrations measured in "the absence of known or potential asbestos emission sources" from the 1960s until the 2000s and reported a mean ambient fiber concentration of 0.00093 f/cc (range: non-detect – 0.050 f/cc) which corresponds to a mean lifetime cumulative exposure of 0.0651 f/cc-year (range: non-detect – 3.5 f/cc-year) (Abelmann et al. 2015, p. 754). It is important to note that the analysis conducted by Abelmann et al. included PCM measurements, which do not distinguish asbestos fibers from other fibers and "may overestimate the true asbestos fiber concentration compared to TEM" measurements in combination with PCM (Abelmann et al. 2015). Similarly, the ATSDR reported a worldwide ambient outdoor range of 0.00001 f/cc for rural areas and 0.0001 f/cc for urban areas based on TEM; the Health Effects Institute- Asbestos Research (HEI-AR) stated that "asbestos fibers of the dimensions most relevant to human health (that is, fibers longer than 5 µm)" were included in these estimates, although the data or studies relied upon for these values were not specified and therefore had unknown relevance to the U.S. population specifically (ATSDR 2001; HEI-AR 1991). Although outdoor ambient asbestos concentrations reported in the literature are generally lower than reported indoor ambient asbestos concentrations, a comparative analysis of airborne asbestos concentrations measured inside and outside 49 buildings performed by Crump and Farrar (1989) suggested that "[n]o statistically significant differences were detected in asbestos levels between indoors and outdoors" (Crump et al. 1989, p. 51).

The U.S. population spends more time indoors than outdoors each day. According to the U.S. EPA Exposure Factors Handbook (2011), an individual spends on average 20 hours indoors (range: 19.0-24 hours) per day and four hours outdoors (range: 0.0-5.0 hours) per day, weighted for age differences over a 70-year lifetime (USEPA 2011). Considering the lowest and highest measured asbestos-specific airborne concentrations of fibers reported in the literature for the U.S., I calculated the range of lower bound and upper bound U.S. lifetime ambient asbestos cumulative exposures based on the number of hours per day, on average, a person spends indoors and outdoors (Lee et al. 2008; Nolan et al. 2001; ATSDR 2001; Nicholson 1987; Crump et al. 1989; Heffelfinger et al. 1972). The lifetime ambient cumulative exposure range using this approach ranged from 0.002 to 0.4 f/cc-yr (**Table 1**).

Table 1. Lifetime ambient cumulative exposure range based on the lowest and highest measured asbestos-specific airborne fiber concentrations.[a b]

Location	Hours	Lower Bound (f/cc)	Upper Bound (f/cc)
Indoor	20	0.00003	0.006
Outdoor	4	0.000003	0.0047
24-hr TWA (f/cc)		0.00003	0.006
Cumulative Exposure 70 years (f/cc-yr)		**0.002**	**0.4**

[a] Based on measurement data for fibers ≥ 5μm in length and asbestos-specific, when possible; for comparison, historic converted data in ng/m^3 were also considered

[b] References: ATSDR 2001; Lee & Van Orden 2008; Nolan & Langer 2001; Nicholson 1987; Heffelfinger et al. 1972; Crump and Farrar 1989

This combined indoor and outdoor ambient cumulative exposure range is consistent with the indoor background cumulative exposure range reported by the ATSDR, given the average number of hours that individuals spend indoors each day according to the U.S. EPA. It should also be noted that if the lower bound worldwide outdoor ambient concentration reported by ATSDR and HEI of 0.00001 f/cc were used in this calculation instead, the resulting cumulative exposure would remain the same. Further, it is possible that these values may underestimate historic ambient cumulative asbestos exposures. According to Abelmann et al., "ambient asbestos concentrations generally increased from the 1960s through the 1980s, after which they declined considerably" (Abelmann et al. 2015, p. 761). And finally, all of these ambient cumulative exposure values for the general U.S. population would be higher if converted to an equivalent occupational cumulative exposure potential rather than the environmental cumulative exposure potential reported above (i.e., cumulative exposure potential over 2080 hours per occupational year compared with 8760 hours per environmental year). Such a conversion allows for a more direct comparison to epidemiological evidence of the cumulative asbestos exposure potential associated with disease. Researchers have reported that this comparison factor is 4.2 (Camus et al. 2002; Reid et al. 2008). Using the factor of 4.2 results in an equivalent occupational cumulative exposure range of 0.0084 f/cc-year to 1.68 f/cc-year, compared to the environmental cumulative exposure range of 0.002 to 0.4 f/cc-year.

Studies that have conducted air monitoring of ambient indoor and outdoor air have found measurable concentrations of both chrysotile and amphibole fibers, including tremolite, actinolite, amosite, and anthophyllite fibers (Cal/EPA Air Resources Board 2015; Lee et al. 2008; Baxter et al. 1983b, 1983a; Crump et al. 1989). According to Nicholson (1987) "asbestos of the chrysotile variety has been found to be a ubiquitous contaminant of air" (Nicholson 1987, p. 7). As reported by the ATSDR, a study of indoor air in homes, schools, and other buildings that contain asbestos materials found that both chrysotile and amphibole fibers are measurable in ambient air (Lee et al. 1992). Similarly, Abelmann et al. stated that their study was a combined analysis of data for all fiber types (Abelmann et al. 2015).

A number of published epidemiology studies have suggested that exposures to ambient asbestos concentrations of any fiber type are not associated with a significantly increased incidence of asbestos-related disease (Price et al. 2004, 2005; Teta et al. 2008; Moolgavkar et al. 2009; Antman et al. 1997; McDonald 1985; McDonald et al. 1994; Moore et al. 2008). For example, Price and Ware (2004) state that although women's environmental exposures would likely have increased since the 1930s with the increasing use of asbestos in the U.S., "the mesothelioma risk for women has not increased" (Price et al. 2004, p. 111). They note that "[e]nvironmental exposure levels, although increasing, have not triggered a risk response in women. Therefore, those exposure levels must have been below a threshold for mesothelioma" (Price et al. 2004, p. 111). Further, a recent study that I conducted with several colleagues (Glynn et al. 2018) indicated that there was no increase in incidence rates of pleural mesothelioma among females in urban versus rural areas in the U.S. between 1973 and 2012, despite measured differences of up to 10 fold or more in ambient airborne asbestos concentrations between these different geographical areas (Glynn et al. 2018). These results suggest that ambient exposures to asbestos over a wide range of background concentrations have not significantly affected the incidence of pleural mesothelioma in the U.S. over the past 40 years, and that each incremental fiber exposure cannot be assumed to contribute to disease risk at similarly low concentrations.

OSHA noted that, based on widely varying background levels of asbestos and the technological feasibility of measuring levels below 0.1 f/cc in the workplace, "the Agency cannot make the general statement that any exposure above ambient background levels presents a significant risk" (Jeffress 1999). Moreover, the U.S. EPA stated that "[e]xtrapolation of risks of asbestos cancers from occupational circumstances can be made, although numerical estimates in a specific exposure circumstance have a large (approximately tenfold) uncertainty" and acknowledged that, "[b]ecause of this uncertainty, calculations of unit risk values for asbestos at the low concentrations measured in the environment must be viewed with caution" (USEPA

1986a, p. 2). The policies of the U.S. EPA and NIOSH state that when the mode of action for any carcinogen is unknown, a linear no-threshold extrapolation model is to be used (NIOSH 2017; USEPA 2017). The U.S. EPA has reported that the risk assessment procedures set forth in their guidelines are more likely to overstate than understate risk, and linear extrapolation models "[do] not necessarily give a realistic prediction of the risk" and the "true value of the risk is unknown, and may be as low as zero" (USEPA 2005; 1986b, p. 13).

OSHA Standards, Warning Label Requirements, and Exemptions Over Time: Encapsulated Products

A notable exception to the on-going evaluation of end-user exposures associated with asbestos-containing products in the 1970s and 1980s was the use of products that were considered encapsulated. It was recognized well before 1980 that encapsulated products did not pose an exposure concern consistent with friable asbestos-containing products.

In the 1930s, researchers acknowledged the risk of asbestosis for those employed in the asbestos processing and manufacturing industries, except where processes involved "articles composed wholly or partly of woven asbestos impregnated with bitumen or other bond of an adhesive nature" (Lanza 1938, p. 391; Home Office 1935). Asbestos industry compensation programs for the workers at risk did not apply to those working with such asbestos products that included an adhesive binder (Lanza 1938).

In 1970, Selikoff noted that products in which "the asbestos is 'locked in' - that is, it is bound with cement or plastics or other binders" would result in no significant release of asbestos fibers in either working areas or the general environment (Selikoff 1970).

No known requirements for labeling of asbestos-containing products existed prior to 1970s (Kopelovich et al. 2014). In 1972, OSHA first required that "[c]aution labels shall be affixed to all raw materials, mixtures, scrap, waste, debris, and other products containing asbestos fibers, or to their containers, except that no label is required where asbestos fibers have been modified by a bonding agent, coating, binder, or other material so that during any reasonably foreseeable use, handling, storage, disposal, processing, or transportation, no airborne concentrations of asbestos fibers in excess of the exposures limits ... will be released" (OSHA 1972b, p. 11321). It was not specified in the federal register who or what party was responsible for this labeling requirement.

OSHA's Hazard Communication Standard

In 1983, OSHA promulgated the Hazard Communication Standard that required "chemical manufacturers and importers to assess the hazards of chemicals which they produce or import, and all employers in SIC Codes 20 through 39 (Division D, Standard Industrial Classification Manual) to provide information to their employees about the hazardous chemicals to which they are exposed" (OSHA 1983a, p. 53340). The standard also indicated that the "chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked with (i) Identity of the hazardous chemical(s); (ii) Appropriate hazard warnings; and (iii) Name and address of the chemical manufacturer, importer, or other responsible party" (OSHA 1983a, p. 53343).

An OSHA directive effective March 20, 1998, provided clarifications to and interpretations of Hazard Communication Standard (HCS) provisions where "significant interpretations have been necessary to ensure uniform enforcement and understanding" (OSHA 1998b). OSHA instructed that only chemical manufacturers and importers were required to perform hazard determinations on the chemicals they produced or imported. Distributors and employers could choose to perform their own evaluation, but an employer could also rely on the hazard determination performed by the manufacturer. The new language in the February 9, 1994, Final Rule indicated that manufacturers were to consider the "health *risk* to downstream users when components of a mixture could be released", whereas the previous language used the term 'health *hazard*' (OSHA 1998b). The language change was due to the recognition that "hazard is an inherent property of the chemical", but "[h]ealth risk is a function of the inherent hazard and the exposure level" (OSHA 1998b). According to the inspection guidelines, a "complete exemption from all requirements of the HCS applies" to manufactured items that, "under normal conditions of use it does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical ... and does not pose a physical hazard or health risk to employees" (OSHA 1998b). Further, the directive instructed that any substance "inextricably bound in a product is not covered under the HCS"; for example, if a hazard determination for a product revealed that a substance was bound and "under normal conditions of use or during foreseeable emergencies cannot become airborne and, therefore, cannot present an inhalation hazard", then that substance "need not be indicated as a hazardous ingredient since it cannot result in employee exposure" (OSHA 1998b).

OSHA's Asbestos Standards and Encapsulated Product Language

In 1986, OSHA's updated asbestos regulatory language required that signs and labels "be posted at each regulated area where occupational exposures could exceed the PEL," except for the two following exempted situations for which no warning label or MSDS was required: "(1) [a]sbestos fibers have been modified by a bonding agent, coating, binder, or other material, provided that the manufacturer can demonstrate that during any reasonably foreseeable use (including handling, storage, disposal, processing, or transportation) employee exposure will remain below the action level; or (2) asbestos is present in a product in concentrations less than 0.1%" (OSHA 1986, p. 22698-22699). This labeling exemption was intended for products including brake pads and other automotive friction materials because of the encapsulated nature of asbestos in these products.

This exemption still stands today; specifically, the 1994 update to the OSHA asbestos standard stated that no label is required on products in which "[a]sbestos fibers have been modified by a bonding agent, coating, binder, or other material, provided that the manufacturer can demonstrate that, during any reasonably foreseeable use, handling, storage, disposal, processing, or transportation, no airborne concentrations of asbestos fibers in excess of the permissible exposure limit and/or excursion limit will be released, or ... [a]sbestos is present in a product in concentrations less than 1.0 percent by weight" (OSHA 1994, p. 41089-41090).

As described above, encapsulated asbestos products were and still are exempt from the OSHA regulations because the airborne fiber concentrations associated with their use are not expected to exceed the OSHA asbestos exposure limits during reasonably foreseeable activities. Available literature, as discussed below, indicates that airborne concentration measurements in brake work exposure studies and industrial hygiene surveys have been consistently below contemporaneous asbestos exposure limits.

Summary

Based on the measurement data in the literature and the OSHA labeling exemptions, brakes were historically considered encapsulated under the OSHA asbestos exposure standards, and are still considered encapsulated today. Many studies of the full-shift asbestos exposure potential during the reasonably foreseeable use of these products have shown exposures to be below or well below the current OSHA 8-hour TWA PEL of 0.1 f/cc, and certainly well below the contemporaneous PELs and action levels. As a result, it would have been reasonable not to

provide OSHA warnings associated with asbestos in these products. This opinion is also consistent with the peer-reviewed literature (Kopelovich et al. 2014).

Employer Responsibility for Worker Health and Safety

It is and always has been well understood that employers are responsible for the safety and well-being of their employees, given their ultimate control over workplace practices and conditions. From old English law to today's worker compensation systems, the employer who supervises and controls the ways and means by which work is done is accountable for the safety and health of his or her employees.

The notion that the health and safety of workers is the responsibility of the employer has a long history. For example, in England, dating back to 1200 A.D., masters were held responsible for the safety of their servants under the law of King Henry I in the 11th and 12th century (Henshaw et al. 2007). However, it was not until rapid industrialization in the United States and elsewhere during the late 1800s and early 1900s, when urban workplaces became more complicated and crowded, that new and unfamiliar workplace hazards highlighted the need for regulatory action regarding workplace health and safety (Henshaw et al. 2007). The need for occupational health and safety oversight, as well as employer accountability for worker well-being, became evident following a number of catastrophic industrial accidents, such as the 1911 Triangle Shirtwaist fire in New York (Henshaw et al. 2007; MacLaury n.d.). The earliest legislation on workplace safety in the United States was state-specific, beginning with Massachusetts' factory safety and health law passed in 1877. Most states followed with their own occupational and health legislation by 1920 (Henshaw et al. 2007; MacLaury n.d.).

On the federal level, workers' compensation laws represented some of the earliest efforts to hold employers accountable for at least the financial burden of workplace injury and loss of life, with an underlying understanding that employers would be motivated to protect against these outcomes. The Federal Employers' Liability Act (FELA) was passed in 1907, specifically to compensate railroad workers for work-related injuries. Many states followed suit, and passed workmen's compensation legislation (Henshaw et al. 2007).

In 1913, the US Department of Labor (DOL) was established to address health and safety concerns associated with a changing and growing workforce (Henshaw et al. 2007). The DOL published the "Safety Code for the Protection of Industrial Workers in Foundries," which described the responsibility of the employer to provide appropriate personal protective equipment to its

employees. Additionally, The Walsh-Healey Public Contracts Act was signed into law in 1936 to provide protections for those employed with contractors engaged in the manufacture or supply of materials for the United States government under the authority of the DOL (U.S. Department of Labor 1936). Although the law was specific to government contractors, the regulation provided a framework for making employers responsible for the health and safety of its workers (U.S. Department of Labor 1952). According to the Walsh Healey Basic Safety Health Requirements reported in 1942, it was "the duty of the employer" to provide employees "effective suitable protective equipment" to protect the eyes and face from hazards, including dusts (U.S. Department of Labor 1942, p. 6). Further, the requirement included that the employer provide personal respiratory protective equipment approved by the U.S. Bureau of Mines "for the particular health hazard involved" (U.S. Department of Labor 1942, p. 8). It was specified that such respiratory protective equipment be "maintained by the employer at no cost to the employee" (U.S. Department of Labor 1942, p. 8).

The National Bureau of Standards within the US Department of Commerce was formed in 1901 as an authoritative body on US measurements and standards. In 1938, the National Bureau of Standards convened a group consisting of industry and government representatives and published the "American Standard Safety Code for the Protection of Heads, Eyes, and Respiratory Organs," which details the responsibility of employers to provide personal protective equipment, including respiratory protection, to its employees based on recognized hazards (NBS (National Bureau of Standards) 1938).

Employer Responsibility in the OSHA Era (December 1970 – Present)

The single most important event in American history for workplace safety and health was the passage of the Occupational Safety and Health Act in 1970. With over 90 million workers in America at that time, Congress made the duties and responsibilities of the employer clear by stating in Section 5 of the Act: "(a) Each employer – (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees; (2) shall comply with occupational safety and health standards promulgated under this Act" (United States 91st Congress 1970). Further, the 1972 OSHA asbestos standard specified that "every employer shall cause very place of employment where asbestos fibers are released to be monitored in such a way as to determine whether every employee's exposure to asbestos fibers" was below applicable limits (OSHA 1972b: p. 11321). However, the expectations for the employer to protect workers against foreseeable workplace hazards has been in place long before this Act (Henshaw

et al. 2007). During the expansion of American industry between 1950 and 1969, professional industrial hygiene associations, such as the ACGIH, were active in the establishment of OELs and other recommended practices for industry. In addition, many employers established their own industrial hygiene departments to improve health and safety programs based upon the voluntary guidance for industry. The federal government, including the Department of Labor, also adopted many of the voluntary standards and work practices for government contractors with requirements that held the employer accountable for worker safety and health (U.S. Department of Labor 1952; Department of Labor 1960).

Two executive orders issued in the early 1970s expanded the provisions of the Occupational Safety and Health Act of 1970 to apply to federal government employees in addition to private sector employees (Peters et al. n.d.-a, n.d.-b). On July 26, 1971, President Richard Nixon signed Executive Order 11612 entitled "Establishment of Occupational Safety and Health Programs in Federal Departments and Agencies" (Peters et al. n.d.-b). This order directed the head of each Federal department and agency to establish an occupational safety and health program in compliance with the Occupational Safety and Health Act of 1970. On September 28, 1974, Present Gerald Ford enacted Executive Order 11807 which replaced Executive Order 11612 (Peters et al. n.d.-a). Executive Order 11807 expanded on the directives contained within Executive Order 11612 in order to improve the effectiveness of each federal agency's Occupational Safety and Health Program. The expanded directives included a directive that the Secretary of Labor issue "detailed guidelines to assist agencies in establishing and operating effective occupational safety and health programs" (Peters et al. n.d.-a, p. 4).

OSHA has continued to reinforce the importance of employer responsibility since the 1970s. In 1991, OSHA published a letter of interpretation that stated, "The primary determination of responsibility for occupational safety and health purposes is which employer directly supervises the employee's day to day work activities and thereby directs the details, means, methods, and processes by which the employee reaches the work objective" (OSHA (Occupational Safety and Health Administration) 1991). Similarly, in 1998, the Occupational Safety and Health Review Commission (a federally appointed panel whose job is to adjudicate OSHA citations) ruled in a case of a subcontractor vs. general contractor: "Each employer is bound by this Act to look out for the safety of his own employees ... Contractual agreements between an employer and another party, stipulating that one party will be solely responsible for the safety of the other's employees, will not negate the original employer's obligation under the Act and does not constitute a defense to a citation" (Rothstein 1998).

The Industrial Hygiene Hierarchy of Controls

The Walsh Healey Basic Safety Health Requirements of 1942 outlined the hierarchy of controls that applied to public contracts. The requirements state that employers "shall have provision for adequate ventilation" for all work rooms, buildings, and places of employment. Additionally, the Walsh Healey Act required that "harmful atmospheric contaminants," including dusts, "shall be reduced or otherwise controlled at the point of origin, by local exhaust" to prevent these materials from entering the breathing zone of workers (U.S. Department of Labor 1942, p. 8). Only in the event that ventilation and local exhaust were "impracticable," employers were to enclose or isolate the work space where the "harmful contaminants" were produced, and any workers entering the enclosed work space were to "be provided with and required to wear suitable type U.S. Bureau of Mines approved respirators or masks when exposed to the harmful contaminants" workers (U.S. Department of Labor 1942, 8). The Walsh-Healey Act allowed for the use of various controls including substitution of the harmful contaminant with a less toxic material, exhaust ventilation, isolation or enclosure of the operations producing the contaminant, process changes, and increased general ventilation (U.S. Department of Labor 1952, p. 23).

The asbestos standard promulgated by OSHA required that administrative or engineering controls be implemented to achieve compliance, when feasible. Personal protective equipment was to be considered when other measures to control exposure were not feasible or possible. OSHA stated that when protective equipment was used as the method to protect employees from exposure, "such protection must be approved for each specific application by a competent industrial hygienist or other technically qualified source" (OSHA 1971b, p. 10504).

National Respiratory Protection Regulations and Standards

Timeline of Key Events

Date	Agency and Topic	Event
1959	ASA, Respiratory Protection	American Standards Association approved Z2.1-1959, the American Standard Safety Code for Head, Eye, and Respiratory Protection (American Standards Association 1959)
1969	ANSI, Respiratory Protection	American National Standards Institute, Inc. (ANSI) approved ANSI Z88.2-1969, the American National Standard Practices for Respiratory Protection (ANSI 1969)

1971, May	OSHA, Respiratory Protection	OSHA's Respiratory Protection Standard, 19 CFR 1910.134 was adopted (OSHA 1972a, p. 119-120, 359; 1982, p. 20804)
1971, May	OSHA, Asbestos	OSHA promulgated regulatory requirements for asbestos, 29 CFR 1910.03 (OSHA 1971b, 10503-10506)
1971, Dec.	OSHA, Asbestos	OSHA published the emergency standard for exposure to asbestos dust, 29 CFR 1910.93a (OSHA 1971a, p. 23207-23208)
1972	OSHA, Asbestos	OSHA published the permanent standard for exposure to asbestos dust, 29 CFR 1910.93a (OSHA 1972b, p. 11318-11320)
1980	ANSI, Respiratory Protection	ANSI approved ANSI Z88.2-1980, an updated American National Standard Practices for Respiratory Protection (ANSI 1980)
1986	OSHA, Asbestos	OSHA published an updated standard for exposure to asbestos dust, 29 CFR 1910.93a (OSHA 1986)
1992	ANSI, Respiratory Protection	ANSI approved ANSI Z88.2-1992, an updated American National Standard for Respiratory Protection (ANSI 1992)
1994	OSHA, Asbestos	OSHA published an updated standard for exposure to asbestos dust (OSHA 1994)
1998	OSHA, Respiratory Protection	OSHA issued its final revised respiratory protection regulation (OSHA 1998a)
2006	OSHA, Respiratory Protection	OSHA published legally enforceable Assigned Protection Factors (APFs) for respirators (OSHA 2006)
2015	ANSI/ASSE, Respiratory Protection	ANSI and the American Society of Safety Engineers (ASSE) adopted ANSI/ASSE Z88.2-2015 Practices for Respiratory Protection (ASSE 2017)

American Standard Safety/American National Standards Institute (ASA/ANSI) Respirator Standards

- Z2.1-1959 American Standard Safety Code for Head, Eye, and Respiratory Protection

In 1959, the American Standards Association approved Z2.1-1959, the American Standard Safety Code for Head, Eye, and Respiratory Protection (American Standards Association 1959). The document was a consensus document with voluntary compliance. The Z2.1-1959 standard was a revision of the 1938 version of the standard which was published as part of the National Bureau of Standards Handbook H24 (American Standards Association 1959). It was the 1938 version of the standard that first included respiratory protection (American Standards Association 1959).

Regarding particulates, the standard classifies particulate air contaminants as: 1) toxic particulates that pass into the blood stream, or 2) fibrosis-producing dust such as asbestos, or 3) nontoxic and nonfibrosis-producing particulates (American Standards Association 1959, p. 28).

The Z2.1-1959 standard advised that respirators should be selected based on eight key factors: 1) the nature of the hazard (e.g. particulate vs. gaseous); 2) the severity of the hazard; 3) the type of contaminant; 4) the concentration of the contaminant; 5) the period of required respiratory protection; 6) location of the contaminated air with respect to source of respirable air; 7) activity of the wearer; and 8) the operating characteristics and limitations of the available respirators (American Standards Association 1959, p. 33-36).

The Z2.1-1959 standard stated that respirators were used to supplement other methods of control rather than to substitute for them (American Standards Association 1959, p. 36). The standard explained that respirators may be called for until other control measures can be put into place or in scenarios where other control measures are impracticable.

According to Z2.1-1959, "it is essential that the user be properly instructed in [respirator] selection, use, and maintenance" (American Standards Association 1959, p. 39). The standard stated that "[c]ompetent persons should give such instruction to the supervisors of all groups who may be required to wear respirators" and the "supervisors, in turn, should instruct their men" (American Standards Association 1959, p. 39). The standard explained that the training should include: 1) an explanation of why the respirator is needed, 2) the respirator's operating principle, 3) how to ensure the respirator is in good operating condition, 4) how to properly adjust the respirator, 5) how to properly use and maintain the respirator.

- ANSI Z88.2-1969 American National Standard Practices for Respiratory Protection

In 1969, the American National Standards Institute, Inc., (ANSI) approved ANSI Z88.2-1969, the American National Standard Practices for Respiratory Protection (ANSI 1969). The document was a consensus document with voluntary compliance. AINSI Z88.2-1969 was a revision of the respiratory protection portion of the American Safety Standard Code for Head, Eye, and Respiratory Protection, Z2.1-1959. In revision of Z2.1-1959, it was deemed advisable to separate the portion on respiratory protection into its own separate standard. Unlike Z2.1-1959, AINSI Z88.2-1969 added a section entitled "Recommended Requirements for Codes" for authorities considering establishment of respirator regulations or codes (ANSI 1969).

In the introduction of the AINSI Z88.2-1969 standard, it is stated that "exposure control shall be accomplished as far as is feasible by accepted engineering control methods before considering or instituting the use of respirators" (ANSI 1969, p. 7). Under the section, "Recommended Requirements for Codes", the AINSI Z88.2-1969 standard stated "In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, *the primary objective shall be to prevent atmospheric contamination*" (ANSI 1969, p. 9, italics in original text).

The ANSI Z88.2-1969 standard stated that According to the ANSI Z88.2-1969 standard, minimum training shall include: 1) instruction in the nature of the hazard; 2) explanation of why more positive control is not immediately feasible; 3) a discussion of why this is the proper type of respirator for the particular purpose; 4) a discussion of the respirator's capabilities and limitations; 5) instruction and training in actual use of the respirator; 6) classroom and field training; and 7) other special training as needed (ANSI 1969, p. 24). As was indicated in the Z2.1-1959 standard, the ANSI Z88.2-1969 standard stated that both "supervisors and workers shall be instructed by competent persons" (ANSI 1969, p. 24).

In the section of the ANSI Z88.2-1969 standard entitled "Recommended Requirements for Codes", the standard stated that employers shall provide respirators to employees when such equipment is necessary to protect the health of the employee. The standard specified that the employer shall provide the respirators which are applicable and suitable for the purposed intended. Further, the standard stated that the employer shall be responsible for the establishment and maintenance of a respiratory protective program. The standard stated that the minimal acceptable respiratory protective program shall include the following: 1) written standard operating procedures governing the selection and use of respirators; 2) respirators shall be selected on the basis of the hazards to which the worker is exposed; 3) the user shall be instructed and trained in the proper use of the respirators and their limitations; 4) where practicable, respirators should be assigned to individual workers for their exclusive use; 5) respirators shall be regularly cleaned and disinfected; 6) respirators shall be stored in a convenient, clean, and sanitary location; 7) respirators shall be inspected during cleaning or, for emergency use respirators, at least once per month and after each use; 8) the employer shall maintain appropriate surveillance of the work area conditions and the degree of employee exposure or stress; and, 9) the employer shall regularly inspect and evaluate to determine the continued effectiveness of the program (ANSI 1969, p. 9).

Regarding administration of the respiratory protection program, the ANSI Z88.2-1969 standard stated that the program shall be administered by the plant or company industrial hygiene, health physics, safety engineering, or fire department ,or, in the absence of any such department, by an upper-level superintendent, foreman, or other qualified individual responsible to the principle manager. The standard stated that responsibility for the program shall be vested in one individual (ANSI 1969).

According to ANSI Z88.2-1969, the respirator furnished by the employer shall provide adequate respiratory protection against the particular hazard for which it is designed in accordance with standards established by competent authorities (ANSI 1969, p. 11). The ANSI Z88.2-1969 stated that the correct respirator shall be specified for each job, adding that "[t]he respirator type is usually specified in the work procedures by a qualified individual supervising the respiratory protective program" (ANSI 1969, p. 23). According to the ANSI Z88.2-1969 standard, "[f]requent random inspections shall be conducted by a qualified individual to assure that respirators are properly selected, used, cleaned, and maintained" (ANSI 1969, p. 28).

- ANSI Z88.2-1980: American National Standard Practices for Respiratory Protection

ANSI approved Z88.2-1980, an updated Practices for Respiratory Protection, in May 1980 (ANSI 1980). The ANSI Z88.2-1980 standard was a voluntary consensus standard.

According to Table 5 of ANSI Z88.2-1980, particulate-filter, quarter-mask or half-mask facepiece filters provide a respirator protection factor of 10 based on qualitative testing, or a factor of up to 100 based on quantitative test measurements on each person (ANSI 1980).

- ANSI Z88.2-1992

ANSI approved Z88.2-1992, an updated American National Standard for Respiratory Protection, in August 1992 (ANSI 1992). The ANSI Z88.2-1992 standard was a voluntary consensus standard. According to Table 1 of the ANSI Z88.2-1992 standard, the assigned protection factor of air-purifying half mask respirators was 10 (ANSI 1992).

- ANSI/ASSE Z88.2-2015 Practices for Respiratory Protection

In 2015, ANSI and the American Society of Safety Engineers (ASSE) approved ANSI/ASSE Z88.2-2015, Practices for Respiratory Protection (ASSE 2017). The updated standard incorporates

regulatory and national standards changes that have occurred since the adoption of ANSI Z88.2-1992.

Early OSHA Respiratory Protection Standards

- OSHA 1971 – 29 CFR 1910.134

In May 1971, the newly formed OSHA adopted its Respiratory Protection Standard, 29 CFR 1910.134 (OSHA 1972a, p. 119-120, 359; 1982, p. 20804). The 29 CFR 1910.134-1971 standard was adopted from the ANSI Z88.2-1969 voluntary consensus standard (OSHA 1982, p. 20804).

As was stated in the Z88.2-1969 standard, the 29 CFR 1910.134-1971 standard stated that "In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination" (OSHA 1972a, p. 359). Also as was stated in the Z88.2-1969 standard, the 29 CFR 1910.134-1971 standard stated that prevention of atmospheric contamination "shall be accomplished as far as is feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less-toxic materials)" (OSHA 1972a, p. 359).

As was stated in the ANSI 1969 standard and the Z2.1-1959 standard, the 29 CFR 1910.134-1971 standard stated that is essential that the user be properly instructed in respirator selection, use, and maintenance (OSHA 1972a, p. 361). Likewise, it was stated that both supervisors and workers shall be instructed by competent persons (OSHA 1972a, p. 361).

The text of the 29 CFR 1910.134-1971 standard began with the text from the Section 3 of the Z88.2-1969 standard, "Recommended Requirements for Codes", including the sections regarding employer responsibility and the minimal acceptable respiratory protection program (OSHA 1972a, p. 359; ANSI 1969). The 29 CFR 1910.134-1971 standard contains the same text regarding employer responsibility within the Z88.2-1969 standard.

In addition, in the section about general requirements for personal protective equipment (1910.132), OSHA stated that personal protective devices including respiratory devices shall be "provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in any part

of the body through ... inhalation" (OSHA 1972a, p. 358-359). Further, OSHA stated that "[w]here employees provide their own protective equipment, the employer shall be responsible to assure its adequacy, including proper maintenance, and sanitation of such equipment (OSHA 1972a, p. 359).

Early Provisions of OSHA Asbestos Standards Regarding Respiratory Protection

- OSHA 1971, May – 29 CFR 1910.93

In May of 1971, OSHA published 29 CFR 1910.93, Air contaminants (Gases, vapors, fumes, dust, and mists) in which OSHA promulgated the first legally binding regulatory exposure limit for asbestos (OSHA 1971b, p. 10503-10506).

The 29 CFR 1910.93-May 2971 standard stated that, to achieve compliance with the exposure limit, "feasible administrative or engineering controls must first be determined and implemented in all cases" (OSHA 1971b, p. 10504). The 29 CFR 1910.93-May 2971 standard also stated that in cases "where protective equipment, or protective equipment in addition to other measures is used as the method of protecting the employee, such protection must be approved for each specific application by a competent industrial hygienist or other technically qualified source" (OSHA 1971b, p. 10504).

- OSHA 1971, December – 29 CFR 1910.93a

In December 1971, OSHA published 29 CFR 1910.93a as an emergency standard for asbestos dust (OSHA 1971a, p. 23207-23208). In the standard, OSHA stated that the employer shall establish a respirator program in accordance with the requirements of ANSI Z88.2-1969 (OSHA 1971a, p. 23208). According to the 29 CFR 1910.93a-Dec 1971 standard, the respirators provided by employers to each employee shall be properly inspected, cleaned, repaired and stored (OSHA 1971a, p. 23208).

According to the 29 CFR 1910.93a-Dec 1971 standard, employers shall provide respirators that are approved by the US Bureau of Mines under the provisions of 30 CFR Part 14 (Bureau of Mines Schedule 21B) (OSHA 1971a, p. 23208). OSHA stated in the 29 CFR 1910.93a-Dec 1971 standard, that, for 8-hr TWA exposure concentrations not exceeding 25 f/cc, and 15-minute TWA concentrations not exceeding 50 f/cc, "a reusable or single-use filter type respirator, operating with negative pressure during the inhalation phase of breathing, approved by the US Bureau of

Mines ..., or a valveless respirator providing equivalent protection, shall be used" (OSHA 1971a, p. 23208). For 8-hr TWA exposure concentrations not exceeding 250 f/cc, and 15-minute TWA concentrations not exceeding 500 f/cc, "a powered filter positive pressure respirator approved by the US Bureau of Mines ... shall be used" (OSHA 1971a, p. 23208). For 8-hr TWA exposure concentrations exceeding 250 f/cc, "a type C positive pressure supplied-air respirator approved by the US Bureau of Mines ... shall be used" (OSHA 1971a, p. 23208).

According to the 29 CFR 1910.93a-Dec 1971 standard, "[e]ngineering methods, such as but not limited to, enclosure, vacuum sweeping, and local exhaust ventilation, shall be used to meet the exposure limits ... of this section. Where such engineering methods are not feasible, or do not otherwise reduce the concentrations below those prescribed ..., respiratory protective devices shall be provided and used in accordance with paragraph (c) of this section." (OSHA 1971a, p. 23208).

- OSHA 1972, 29 CFR 1910.93a

In June of 1972, OSHA published an updated 29 CFR 1910.93a as a permanent standard for asbestos dust (OSHA 1972b, p. 11318-11320). According to the 29 CFR 1910.93a-1972 standard, the employer shall establish a respirator program in accordance with the requirements of ANSI Z88.2-1969 (OSHA 1972b, p. 11320-11321). OSHA stated in its 29 CFR 1910.93a-1972 standard that employers are required, within 6 months of the publishing of the standard, to perform personal and environmental monitoring to determine the 8-hr TWA and ceiling fiber concentrations of employees (OSHA 1972b, p. 11321). For employees whose asbestos exposures were reasonably foreseen to exceed the exposure limits, employers were required to perform personal monitoring at least every six months (OSHA 1972b, p. 11321).

In the 29 CFR 1910.93a-1972 standard, OSHA required that employers select respirators that were approved by the Bureau of Mines or by NIOSH under the provisions of 30 CFR Part 11 (OSHA 1972b, p. 11320).

In the 29 CFR 1910.93a-1972 standard, OSHA stated that compliance with asbestos exposure limits shall be met using engineering controls, local exhaust ventilation, particular tools, and work practices such as wet methods (OSHA 1972b, p. 11320). OSHA stated that compliance shall not be achieved using respirators or shift rotation of employees except during the time period necessary to install the engineering controls and institute appropriate work practices, and in

which other controls are either technically not feasible or are insufficient to reduce the airborne concentrations below the exposure limits (OSHA 1972b, p. 11320).

OSHA Respirator Assigned Protection Factors

In 2006, OSHA revised its respiratory protection standard to add definitions and requirements for assigned protection factors (APFs) and maximum use concentrations (MUCs) (OSHA 2006). ANSI standard Z88.2-1969 which was adopted by OSHA in 1971 did not contain APFs for respirator selection (OSHA 2006, p. 50125). In the 1998 final respiratory protection standard, OSHA reserved the sections related to APFs and MUCs pending further rulemaking. In the interim, OSHA stated that employers should take into account the best available information when selecting respirators, including the APFs in the 1987 NIOSH Respirator Decision Logic (RDL) document (OSHA 2006, p. 50125). In 2006, OSHA determined that the class of respirators which included the 3M 8710 would have an APF of 10; NIOSH agreed with OSHA's determination that this class of respirators would have an APF of 10 [see Section IV(C)2].

Industrial Hygiene Knowledge Over Time Regarding Asbestos

With several colleagues, I published a review article regarding the knowledge of asbestos over time within the industrial hygiene community from the early 1900s until the advent of the national health and safety regulatory structure currently in place in the U.S. (early-to-mid 1970s) (Barlow et al. 2017). Following our review of over 1,000 references, it was apparent that the evaluation of the health risks of asbestos was a complex evolution requiring decades of focused research, particularly with respect to exposure assessment (Barlow et al. 2017). Developments over time specifically as they relate to industrial hygiene knowledge of asbestos, asbestos exposure limits (1930s-1970s), and the establishment of U.S. OSHA and NIOSH are discussed in detail in the sections below.

Developments in Industrial Hygiene Knowledge of Asbestos

Industrial hygiene as a profession was in its infancy when asbestos use increased substantially in the early 1900s (Barlow et al. 2017). In this early 1900s timeframe, asbestos was frequently used in the heavy machinery industry, in the building and insulation trades, and in the military. Examples of important uses included in heat-resistant equipment components such as gaskets and brakes; in fire- and heat-resistant building components and piping systems; and for fire protection and insulation on ships. Over time, asbestos has been used in various commercial and

household products such as pipe insulation, fireproof roofing and wall materials, textiles including rope, twine, and yarn, electrical applications, plastics, flooring, paints, plasters, caulks, asphalt, mattresses, theater curtains, medical equipment, baking sheets, and cabinets (Virta 2005; Selikoff et al. 1978). Further, given the heat-resistant properties of asbestos, it was used in clothing for fire and heat protection. For example, in the October 1934 issue of *Popular Science*, asbestos suits and umbrellas used by London firemen were praised as safety devices that enabled the firemen to approach the "most furious blaze" (Unknown 1934, p. 30).

It was in 1930 that very high dust exposure levels in the asbestos manufacturing trades, including mining, milling, and asbestos textile production, were definitively linked to a non-carcinogenic lung fibrosis condition that became known as asbestosis. Merewether and Price (1930) reported that greater than 25% of workers exposed to asbestos in textile manufacturing settings in the United Kingdom developed pulmonary fibrosis, and that the incidence of fibrosis increased with the length of employment. Before 1930, the technology to measure worker exposures was very limited, and therefore restricted the ability of public health professionals to draw conclusions about the relationship between asbestos exposure and health risk (Barlow et al. 2017).

From the 1930s through the 1950s, the vast majority of published studies on asbestos looked at workplace conditions in very dusty asbestos manufacturing settings in which raw asbestos was used. According to Merewether and Price in their 1930 study, their investigation focused on manufacturing "in which there [was] exposure to pure asbestos or asbestos mixed with a very small percentage of cotton or other vegetable fibre" (Merewether et al. 1930). In 1935, a British report entitled "Memorandum of the Industrial Diseases of Silicosis and Asbestosis" identified the manufacturing of asbestos textiles, the making or repairing of insulating slabs and mattresses, and the sawing, grinding, and turning of articles composed wholly or partly of dry asbestos as the industries and processes where asbestosis was likely to occur (Home Office 1935).

From the 1940s through the 1960s, Naval specifications required that amosite asbestos-containing insulation be used for a variety of applications on ships (U.S. Navy 1959b, 1962, 1947). In 1942, the U.S. Navy issued a conservation order to conserve the supply of asbestos for purposes of national defense, mandating "no person shall fabricate, spin, or process in any other way asbestos fibre ... except where such fabrication, spinning or processing is necessary to fill Defense Orders" (Knowlson 1942, p. 436). Chapter 39 of the Bureau of Ships Manual of 1945 describes a number of shipboard applications requiring different types of thermal insulation and lagging. This manual described specifications for asbestos-containing materials for insulation applications based on equipment and temperature considerations (U.S. Navy 1945). Later

revisions of this manual, through at least 1966, maintained specifications for asbestos-containing materials in certain applications (U.S. Navy 1947, 1959a, 1960, 1965, 1966).

Through the 1950s, the ASTM International (formerly known as the American Society for Testing and Materials) had a number of asbestos-product related standards in place. The ASTM is a non-profit organization formed in 1898 to develop international voluntary consensus standards to improve product quality and enhance safety. Standards related to asbestos products included the manufacture of asbestos yarns, asbestos roving for electrical purposes, asbestos tubular sleeving, asphalt-saturated asbestos felts, laminated asbestos thermal insulation, and cellular asbestos paper thermal insulation (ASTM 299-52T; 375-52; 577-52; 628-52; 250-56; C298-56; C299-56) (ASTM 1952a, 1952b, 1952d, 1952c, 1956b, 1956a, 1956c).

In the early 1950s, the first studies began to be formally published about the nature of the fibrosis reaction caused by asbestos in the lungs. According to Vorwald et al. (1951), experiments on fiber dimension yielded information that "the capacity of inhaled asbestos fibers to produce fibrosis [was] determined primarily by factors not chemical in nature" but rather by mechanical factors (Vorwald et al. 1951, p. 18). The authors reported that fibers shorter than about 10 to 20 μm in length were "relatively innocuous" and that fibrosis was primarily caused by fibers in the range of 20 to 50 μm in length (Vorwald et al. 1951, p. 40). It was also reported that when asbestos was ground up so that none of the particles were longer than 20 μm in length, "the fibrosis –producing character of asbestos could be almost eliminated" (Sander 1958, p. 398). The American College of Chest Physicians also noted in 1964 that "grinding the fibers to less than 5 microns in length decreases their capacity to evoke fibrosis in experimental animals" (Hannon et al. 1964, p. 108).

In 1952, it was noted by Dr. Smith that, "It was the consensus of Dr. Gloyne, Dr. Wyers and Dr. Merewether that the nature of the disease asbestosis in England has changed so that it is less common and less severe in individuals whose employment in the industry has taken place only since 1932 [the year when exhaust ventilation devices were installed]. It was the consensus that a lung tumor hazard formerly existed in this industry in Great Britain but that there is no evidence to show that such a hazard continues to exist under the working conditions now prevailing" (Smith 1952, p. 253).

It was in the mid-1950s that the link between asbestos exposure and cancer was formally investigated within the advancing field of epidemiological research (Eckardt et al. 1954). Although there were a number of case reports in the late 1940s and early 1950s about a potential relationship between lung cancer and exposure to asbestos, the interpretation of these case

reports was complicated by the fact that most workers were also smokers (Merewether 1949). Thus, while there was some concern that asbestos alone might cause lung cancer, the data were not convincing through the early 1950s.

In 1955, Sir Richard Doll used a robust epidemiological study design to examine the association between asbestosis and lung cancer in workers in the United Kingdom exposed to elevated asbestos dust for twenty years or more in the asbestos textile industry. His study results indicated that an association between asbestosis and lung cancer existed. Because nearly all of the lung cancer cases that Doll studied were also diagnosed with asbestosis, he believed that asbestosis was a precursor to lung cancer and therefore lung cancer was similarly associated with high levels of asbestos exposure (Doll 1955). Doll concluded that the risk of developing asbestosis and lung cancer should continue to diminish as the industrial hygiene controls suggested by Merewether and Price (1930) were adopted (Doll 1955). Other scientists studying the asbestos-lung cancer association at the time agreed that asbestosis was a necessary precursor of lung cancer. According to Hueper, the Chief of the Environmental Cancer Section of the National Cancer Institute in 1955, "[e]pidemiological data available at present indicate that an increased liability to cancer is limited to the presence of asbestosis of the lung and does not extend to exposure to asbestos without the existence of a pneumoconiosis resulting therefrom" (Hueper 1955). Hueper confirmed in 1957 his belief that the risk of lung cancer was associated with those who were highest exposed, stating that an increased risk of lung cancer existed for miners, textile workers, and brake lining manufacturers (Hueper 1957).

It should be noted that through the 1950s and early 1960s, the industrial hygiene and safety community did not yet fully embrace the association between asbestos exposure and lung cancer. In the second edition of the Patty's Industrial Hygiene and Toxicology textbook in 1958, the section of the book written by Sander about asbestos was referred to as "Asbestosis," and in this section it was noted that "lung cancer is under suspicion as occurring more frequently with asbestosis, especially in England" (Sander 1958, p. 398). Similarly, in 1963, the National Safety Council Data Sheet #531 stated that "[i]t is suspected that lung cancer may be induced by asbestos. However, there is no impressive amount of evidence to support this assumption" (National Safety Council 1963). That same year, the Council on Occupational Health of the American Medical Association voiced a similar opinion (Robin et al. 1963). In 1964, the American College of Chest Physicians stated that "While it has been reported that there may be an enhanced prevalence of pulmonary neoplasia in some asbestos industries (e.g. crocidolite or amosite), or in some locations (e.g. South Africa, England), this does not appear to apply for the

chrysotile industry in North America. This comment applies both with respect to intrapulmonary new growths and to pleural mesothelioma" (Hannon et al. 1964, p. 109).

In addition to the causal association between asbestosis and lung cancer demonstrated by Doll in 1955, research was first published in the early 1960s reporting mesothelioma after crocidolite exposure. In 1960, Wagner et al. found that increased mesothelioma risk was associated with exposure to crocidolite, an amphibole mineral fiber (Wagner et al. 1960). In a follow up study in 1965, Wagner examined populations who lived or worked near crocidolite, amosite, and chrysotile mines or were occupationally exposed via mining or other work in South Africa. While numerous cases of mesothelioma were identified in populations near crocidolite mines, no cases were associated with chrysotile or amosite mines (Wagner 1965).

In October 1964, Dr. Irving Selikoff, a researcher at Mt. Sinai Hospital in New York City, held a conference on the "Biological Effects of Asbestos." The proceedings of this conference were published in late 1965. A notable study discussed at the conference was Dr. Selikoff's report examining a cohort of more than 600 insulation workers that primarily handled amosite-containing insulation (Selikoff et al. 1964, 1965a). This study found a significantly increased risk of death from lung cancer and mesothelioma among insulation workers, a finding that resulted in a key change in the way future asbestos worker studies were conducted, and researchers began to investigate worker cohorts handling other asbestos-containing end-user products.

The debate over the association between asbestos and cancer (both lung cancer and mesothelioma) lasted over many decades. Enterline extensively reviewed the literature from between 1935 and 1965 on these associations (Enterline 1991). Opinions on the likelihood of association were different depending on the country of research origin, and significantly different degrees of association were seen by different researchers. In Europe and Africa, there were more consistent and significant associations noted for both lung cancer and mesothelioma, most likely due to fiber type differences (Enterline 1991; Wagner et al. 1960; Doll 1955; Wedler 1943b, 1943a; Braun et al. 1958; Gilson 1965; Nordmann 1938).

In 1969, the first edition of the Insulation Hygiene Progress Reports appeared in the Asbestos Worker journal of the International Association of Heat and Frost Insulators and Asbestos Workers union. These reports provided updates on the Insulation Industry Hygiene Research Program, which represented "the nation's first cooperative effort by an international labor union, industry, and science, consulting with government to undertake a health research program for industrial workers" (Selikoff 1969: no. 1, p. 1). Dr. Selikoff was the director of the program in a

joint agreement with the Mt. Sinai Environmental Sciences Laboratory. According to the first report, published in the spring of 1969, "the primary purpose of the combined industrial hygiene and preventive engineering research program [was] to develop improved methods that will minimize exposure of insulation workers to dust and fumes encountered in their jobs" (Asbestos Worker Journal 1969-1972, no. 1, p. 1). Key initiatives of the program included developing a new respirator for insulation workers that was "efficient, comfortable, and disposable," sprayed fiber controls, "dustless [insulation] mixing bags," and development of effective dust collectors for mechanized equipment such as band saws or textile saws (Asbestos Worker Journal 1969-1972, no.1, p. 1, no. 3, p. 1).

Developments in Asbestos Exposure Limits Over Time, 1930s - 1970

In 1933, Dr. E.R.A. Mereweather, the Medical Inspector of Factories in England, published an analysis in which he stated that, "from examination of the varying conditions of exposure to dust amongst 'spinners' in individual factories, it appeared reasonable to infer that the exposure of workers in this group to dust, as a whole, was not greatly in excess of the maximum safe limit" and that "the conditions arising from flyer spinning carried on without exhaust under good general conditions was considered as the safe criterion and was termed the 'dust datum'" (Merewether 1933, p. 115-116). In 1930, Merewether presented five airborne dust concentration measurements for activities characterized as asbestos "spinning" using the Owens jet apparatus. These measurements were reported in the number of particles per cubic centimeter (p/cc), ranging from 620 p/cc to 6,044 p/cc. Converting these concentrations to mppcf results in a 'dust datum' range of approximately 17.6 to 171.2 mppcf (Merewether 1930). In 1933, Merewether made the distinction between "ring spinning" and "flyer spinning", characterizing flyer spinning as less dusty and more consistent with the levels of dustiness measured for braiding and plaiting activities (Merewether 1933, p. 115). Merewether also noted that "most" of the crystalline asbestos particles collected during the airborne dust collection were "iron containing" (Merewether 1930, p. 247).

In 1934, Merewether also explained that a "conference of asbestos textile manufacturers and representatives of the Home Office" in the U.K. government was arranged to "consider these practical difficulties and the best methods which could be adopted generally for suppressing dust in manufacturing and other processes" (Merewether 1934, p. 153). Following the conference, it was decided "to set up a joint committee to consider the problem in detail and to collect all information available concerning dust suppressing methods" (Merewether 1934, p. 153). The

committee agreed on the airborne concentration standard recommended by Dr. Merewether for dust levels and stated in their conclusions that "For practical purposes, the conditions arising from flyer spinning carried on, without exhaust under good general conditions may, it seems to the Committee, be taken as the 'dust datum.'" (Merewether 1934, p. 154).

In 1938, the U.S. Surgeon General performed an important study assessing the asbestos exposure potential for more than 500 U.S. male and female textile manufacturing workers (Dreessen et al. 1938). The results of this study confirmed that the magnitude of the airborne concentration of dust and the duration of exposures were associated with the rate of asbestosis. In their exposure study, Dreessen et al. (1938) recommended maintaining an airborne exposure concentration in the workplace of 5 million particles per cubic foot (mppcf) or less. According to the authors, "[i]t would seem that if the dust concentration in asbestos factories could be kept below 5 million particles ..., new cases of asbestosis probably would not appear" (Dreessen et al., 1938: p. 117).

Before 1940, there were no national standards or guidelines regarding acceptable exposures to chemicals or particulates in the workplace, including asbestos. By 1942, a number of states had developed some guidelines for the use of specific chemicals, including asbestos, but these were often targeted for selected industries (LaNier 1984; Frederick 1984). Regarding asbestos specifically, a number of states adopted the 5 mppcf maximum permissible concentration for asbestos based on Dreessen's recommendation, including California, Colorado, Massachusetts, Michigan, North Carolina, Oklahoma, Texas, and Pennsylvania, while South Carolina adopted a 15 mppcf guideline (LaNier 1984).

The National Conference of Governmental Industrial Hygienists (NCGIH) and American Industrial Hygiene Association (AIHA) were formed in 1938 and 1939, respectively. In 1946, the NCGIH changed its name to the American Conference of Governmental Industrial Hygienists (ACGIH). The AIHA and ACGIH are professional organizations with memberships consisting of industrial hygienists and other occupational and environmental health professionals. By the early 1940s, the ACGIH had formed a committee to develop and recommend occupational exposure limits to its membership for chemicals and physical agents commonly found in the workplace (Baetjer 1984). ACGIH recognized the need to support increased consistency in state and local regulatory and guidance bodies with respect to the variety of recommendations developed for the protection of workers (Stokinger 1981).

In 1946, the ACGIH adopted a value of 5 mppcf as the recommended full-shift daily exposure limit for all mineral types of asbestos based on Dreessen et al. (1938), in which they noted that

"massive exposures" to asbestos occurred (ACGIH 1968, p. 188). This eight hour TWA TLV for asbestos remained the acceptable ACGIH exposure limit through the 1950s and up until 1968 (ACGIH 2001).

Throughout the 1940s and 1950s, industrial hygienists continued to associate hazardous asbestos exposures with workers in the asbestos mining, milling, and manufacturing trades who routinely handled raw asbestos fibers (Ayer et al. 1965; ACGIH 1968; Shapiro 1970). Exposures exceeding the 5 mppcf TLV were not associated with workers handling asbestos-containing products, and this was supported by the first large-scale epidemiological study to measure the exposures to end-users of asbestos-containing products. Published in 1946, this study examined the exposure potential and health status of naval pipe covering workers at four separate shipyard locations (Fleischer et al. 1946). The authors reported that three of the 1,074 workers evaluated had developed asbestosis after employment as pipe coverers for more than 20 years. Another 48 pipe coverers who worked for more than 10 years reportedly did not develop asbestosis. Airborne dust concentrations attributable to asbestos for certain activities such as insulation layout and cutting, sewing and fabrication, cement mixing, and grinding, were reported to be less than the recommended ACGIH TLV of 5 mppcf, although total dust concentrations were found to exceed this level. Only isolated activities in the study, such as the use of a band saw to cut insulation, were reported to result in airborne asbestos concentrations above 5 mppcf. The authors noted that the asbestos exposures associated with asbestos manufacturing settings such as asbestos textile manufacturing would "differ widely" from exposures associated with the use of asbestos-containing products (such as pipe covering activities) (Fleischer et al. 1946, p. 13). They further reported that "[i]n textile plants workers usually continue at specific jobs with fairly constant dust exposures for some years, whereas the pipe coverer may rotate between shop and ship and from small to large ship compartments with a wide variation in dust exposure" (Fleischer et al. 1946, p. 13). They also indicated that the asbestos content of insulation materials could vary widely (10-95%). In their conclusions, the authors stated that, "[s]ince each of the three cases of asbestosis had worked at asbestos pipe covering in shipyards for more than 20 years, it may be concluded that such pipe covering is not a dangerous occupation" (Fleischer et al. 1946, p. 16).

In 1951, the Walsh-Healey Contracts Act was revised by the U.S. Department of Labor to adopt the ACGIH TLV for asbestos of 5 mppcf (Department of Labor 1951). The Walsh-Healey Act stated that companies that entered into contracts of over $10,000 with the federal government were required to provide a safe workplace for their employees and assure that employees were not being exposed above specific occupational guidelines (OSHA 2002). The value for asbestos of 5 mppcf was further incorporated in the 1952, 1960, and 1966 revisions of the Walsh-Healey Act

(Department of Labor 1952, 1960, 1966). The U.S. Military also adopted these early occupational exposure limits, and in 1955, the Naval Bureau of Medicine and Surgery sent a memorandum to all locations and ships stating that the Navy should adopt the TLVs established by ACGIH, including the asbestos TLV, in order to "provide guidance toward the reduction of potential health hazards encountered in the industrial environment for both military and naval civilian personnel" (United States Navy 1955, p. 1).

Throughout the 1940s and well into the 1950s and early 1960s, the safety and health community continued to remain focused on asbestos exposure potential in the very dusty trades, including miners and millers handling raw asbestos mineral fibers and workers in asbestos product manufacturing settings. Industrial hygienists continued to consider mineral fiber concentrations below 5 mppcf (the "Dreessen Standard") unlikely to present an increased risk of asbestos-related disease, and the handling of asbestos-containing end-user products was considered unlikely to produce exposures at concentrations sufficient to put workers at increased risk of developing asbestos-related disease. Similarly, in 1953, Isselbacher et al. continued to refer to the 'dust datum' level established through the work of Merewether and the U.K. committee established to determine practical standards for dust suppression as a "safe level" (Isselbacher et al. 1953).

Another early worker exposure end-user product study was published by Marr in 1964, which, unlike Fleischer et al., 1946, demonstrated that exposures to insulators could exceed the 5 mppcf standard (Marr 1964). During a variety of insulation installation and removal tasks at Long Beach Naval Shipyard, Marr found concentrations of fibers 3-60 µm in length ranging from less than 1 mppcf to 8.0 mppcf (Marr 1964).

Despite the recent publications in the scientific literature about the association between asbestos and lung cancer and mesothelioma, in the early 1960s, the ACGIH reaffirmed the TLV for asbestos at 5 mppcf (LaNier 1984). However, a call to lower the TLV began at the Biological Effects of Asbestos conference in 1964.

Up until the mid-1960s, impingers and midget impingers were the most common sampling methods used to collect asbestos dust in the air in the U.S. In 1969, the Bureau of Occupational Safety and Health within the U.S. Department of Health, Education, and Welfare published a document on the procedure for using the Millipore sampling method for measuring airborne asbestos fiber concentration (Bayer et al. 1969). The British Asbestos Research Council published a similar method in the same year. These sampling methods collected fibers in the air on a

membrane filter, which allowed for the analysis of airborne fibers specifically, rather than just the concentrations of all particulates collected from the air (OSHA 1997; Ayer et al. 1965; Bayer et al. 1969; Barlow et al. 2017). This was an important development in assessing asbestos exposures in the workplace, since it had been established that it was the longer fibers that were of greatest concern in determining disease risk (Vorwald et al. 1951).

Despite the limitations of the impinger sampling method for asbestos, asbestos exposure measurement data collected using the impinger still generally correlated with much of the epidemiological data collected prior to this period of history. According to Ayer et al. (1965), "the incidence and severity of asbestosis increased with increasing dust exposure and ... those workers exposed to dust concentrations of less than 5... mppcf [using the standard impinger method] did not develop asbestosis even after long-continued exposure" (Ayer et al. 1965, p. 274). According to worksite studies, it was determined that 1 mppcf using the impinger method was roughly equivalent to 6 fibers per milliliter of air, or f/mL (also equivalent to f/cubic centimeter, f/cc) when counting fibers greater than 5µm in length using the membrane filter method; therefore, the 5 mppcf exposure limit determined by the impinger method was roughly equivalent to 30 f/cc using the membrane filter method (Ayer et al. 1965; Lynch et al. 1968). However, this conversion factor will be variable depending upon the worksite and the nature of materials used (Ayer et al. 1965).

In 1968, the committee on Hygienic Standards of the British Occupational Hygiene Society (BOHS) first recommended a limit for chrysotile of 2 f/ml as an 8-hour TWA exposure limit (ACGIH 1968). This level was set based on a 50-year working lifetime exposure, and was derived based on the concept that in order to avoid asbestosis, the chrysotile asbestos fiber burden should be below 100 fiber/ml-years. Fiber/ml-years are calculated by multiplying the eight-hour TWA exposure by the number of years exposed, assuming exposures occur five days a week, 50 weeks a year. Also in 1968, the ACGIH proposed to change their asbestos TLV and recommended a new ceiling limit of 5 mppcf and an eight-hour TWA TLV of 2 mppcf or 12 f/cc for fibers greater than 5 µm in length. This proposed change was adopted under the Walsh-Healey Act revision of 1969. Again in 1970, ACGIH proposed to lower the TWA TLV to 5 f/cc for fibers longer than 5 µm in length, and added a short-term exposure limit of 10 f/cc, longer than 5 µm in length, as averaged over 15 minutes. ACGIH ultimately adopted the lower TWA TLV for asbestos in 1974 at 5 f/cc greater than 5µm in length and included the designation "human carcinogens ... with an assigned TLV" (ACGIH 1974a; 1974b, p. 46).

Establishment of U.S. OSHA and NIOSH

The first U.S. Occupational Safety and Health Act was passed at the end of 1970, and in 1971 the newly formed Occupational Safety and Health Administration (OSHA) promulgated regulatory requirements for the first time for asbestos that were legally binding in a majority of workplaces in the United States. Authorized by Congress under the OSH Act, OSHA adopted the existing Walsh-Healey standards, which included the 12 f/cc or 2 mppcf eight-hour TWA for asbestos, referred to as a Permissible Exposure Limit (PEL) (OSHA 1971b). The PELs for asbestos over time have been based on both an eight-hour TWA using the same methodology established by the ACGIH TLVs, as well as a 15- or 30-minute short-term TWA for excursions above the eight-hour TWA. In 1972, OSHA reduced the asbestos PEL to 5 f/cc as an eight-hour TWA, and created a 15-minute peak exposure value of 10 f/cc for all asbestos forms. The 1972 standard included a reduction of the eight-hour TWA PEL to 2 f/cc in 1976 (OSHA 1972).

The 1972 OSHA asbestos standard regulated only fibers longer than 5 µm in length (OSHA 1972b). Since 1971, OSHA has employed the filter membrane sampling with phase contrast microscopy (PCM) analysis for the evaluation of airborne asbestos fiber concentrations at work sites in the U.S. for determining airborne concentrations of fibers per cubic centimeters; this method became a requirement under the OSHA asbestos standards in 1972. However, it should be noted that PCM does not discriminate between asbestos fibers and other dimensionally similar fibers. This methodological limitation can lead to overestimations of airborne asbestos concentrations. Transmission electron microscopy or TEM analysis is often used to differentiate between asbestos mineral fiber types (e.g., chrysotile, amosite, and crocidolite) and to distinguish asbestos fibers from non-asbestos fibers. Since the PEL is based on PCM data, TEM analysis is generally used as a secondary method to determine the fraction of asbestos fibers in the total airborne fiber count for comparison with PCM data. This asbestos fiber-specific fraction of the total measured PCM fibers is often called the PCM-equivalent asbestos fiber concentration, or PCME (Sahmel et al. 2014a; Barlow et al. 2017).

In 1973, Dr. Herb Stokinger, the Chairman of the ACGIH TLV committee and Chief of the Toxicology Branch of the U.S. Public Health Service, wrote a letter to the TLV committee stating that recent asbestos epidemiology studies had shown a threshold response for carcinogenicity and asbestos. He calculated in the letter a "margin of safety" for "all types of asbestos related disease, cancers and asbestosis" at the ACGIH TLV of 5 f/cc as averaged over an eight-hour work day (Stokinger 1973). For a 50-year working lifetime at the 5 f/cc eight-hour TWA, the safety factor was estimated at 3.1, equivalent to a cumulative exposure of 250 f/cc-yrs.

Regarding the levels of asbestos exposure necessary to cause disease, published references in the early 1970s clearly demonstrated that this issue had not yet been resolved. According to NIOSH in 1972, "the scant data and the long latent period for the development of bronchogenic cancer and mesothelioma do not permit the establishment of the dose-response relationship [for asbestos] at this time" (NIOSH 1972). Similarly, in 1970, regarding asbestos exposures, Roach stated that, "to derive hygiene standards for an air contaminant which provide a known degree of protection against a health hazard, it is necessary to have a body of data showing the amount of air contaminant to which people are exposed and the corresponding effects or lack of them in the people...Our present information is very imprecise, particularly in terms of the practical consequences of specific hygiene standards" (Roach 1970, p. 14). Nearly all notable exposure studies of occupations in which the employees were potential end users of asbestos-containing products were not published until the 1970s, including for auto mechanics, electricians, dry wall workers, and insulation workers (Hickish et al. 1970; Sawyer 1977; Rohl et al. 1975; Nicholson et al. 1972; Nicholson 1976). It was not until these studies began to be published that the relative exposure potential associated with end users of different asbestos-containing products was understood in terms of airborne fiber concentrations. It was also important that these were among the early exposure studies to report exposures using the PCM analytical method (f/cc) rather than total suspended particulates (mppcf). Without these data, the risk of asbestos exposure could not be quantified in the terms used today by the scientific community (Barlow et al. 2017). For example, in 1977, Rohl et al. stated that with respect to chrysotile-containing brakes specifically, there was a need for "Epidemiological studies of the mortality experience of exposed workers" (Rohl et al. 1977), p. 36).

In 1975, OSHA published a Notice of Proposed Rulemaking to revise the standard for occupational exposure to asbestos (OSHA 1975). In the notice, OSHA stated that "in very recent time," asbestos in commercial forms had come to be associated with bronchogenic carcinoma (OSHA 1975: p. 47653). Regarding smoking, OSHA reported that a study by Hammond and Selikoff (1973) had confirmed earlier findings indicating that "non-smoking asbestos workers had few lung cancers while those who smoked had much more lung cancer than would have been expected had they not been asbestos workers" (OSHA 1975: p. 47655). It appears likely that smoking among workers complicated the ability of researchers and government regulators to characterize the quantitative association between asbestos exposure and lung cancer.

With respect to asbestos dose-response relationships, a 1980 OSHA/NIOSH report reported that "the exact nature of the dose-response relationships may be subject to considerable debate. This

is ... primarily because of problems of exposure estimation. Methods of measuring dust levels have changed over time with respect to sampling instrument (thermal precipitation vs. midget impinger vs. membrane filter), location of sampling (personal vs. area), and dust counting (particles vs. actual fibers) and/or evaluation techniques (whole fields vs. eyepiece graticule)" (NIOSH/OSHA 1980: p. 31).

Mr. LaFrentz's Use of Respiratory Protection at General Dynamics/Lockheed Martin

Mr. LaFrentz testified that during the honeycomb or coupon drilling process, he "had a mask on" (LaFrentz Vol. I: p. 72, l. 7, p. 73). He stated that he was not aware of any policies that required him to use a dust mask while performing the coupon drilling work (LaFrentz Vol. I: p. 74). He did not recall whether he had a dust mask on the very first time he started drilling (LaFrentz Vol. I: p. 74). He stated that he was first prompted to request a dust mask for this work because he was "trying to get away from all the black dust and smell"; he later described a "black fog" (LaFrentz Vol. I: p. 74, l. 25 – p. 75, l. 1; Vol. 2: p. 168). He indicated that he would wear the mask "all the time"(LaFrentz Vol. I: p. 80, l. 17).

Mr. LaFrentz believed that the mask "was a 3M dust protector" and that it "was 8710" (LaFrentz Vol. I: p. 78, l. 4, 7). He reported that he did not have any facial hair during that time or ever (LaFrentz Vol. I: p. 78-79). He believed that he wore the same mask during the three years he was a drill press operator (LaFrentz Vol. I: p. 81). He recalled that "most of the time", he would wear the same mask all day (LaFrentz Vol. I: p. 82, l. 3). He later clarified that it was "probably a week until [he] got the mask" after he started drilling the panels (LaFrentz, Vol. 2: p. 106, l. 8).

Mr. LaFrentz testified that he did not ever see an instruction sheet with the 3M 8710, or any product warnings, literature, brochures, or advertisements (LaFrentz Vol. 2: p. 108).

C_{8hr}: A Review of the Data from Relevant Peer-Reviewed and Government Publications and on Measured Airborne Fiber Concentrations during Work with Adhesive Products

Airborne Fiber Concentration Data Associated with Adhesive Products

Mr. LaFrentz agreed in his testimony that there was a document produced as Exhibit Plaintiff 2 to his deposition that addressed the use of adhesive in the honeycomb aircraft panels he described working with at General Dynamics for approximately two days per month over three years between 1979 and 1981 or 1982 (LaFrentz Vol. 2: p. 162). Specifically, the document

described the material as follows: "FMS 3018 is used in adhesive of P 653 Panels" (LaFrentz Exhibit Plaintiff 2).

The use of chrysotile asbestos in adhesive composites is considered an encapsulated product. Consistent with this characterization of the asbestos exposure potential associated with composite and adhesive materials, at least one peer-reviewed published study has indicated that the use of asbestos-containing coatings, mastics, epoxies, adhesives, and similar products in occupational settings is likely to result in very low concentrations of airborne asbestos, if these concentrations are not below the limit of detection. Such airborne fiber concentrations would have been below both historical and current occupational exposure limits for asbestos, and could be indistinguishable from background concentrations of asbestos in industrial environments.

Paustenbach *et al.* (2004) published a peer-reviewed article titled *Occupational exposure to airborne asbestos from coatings, mastics, and adhesives* in the Journal of Exposure Analysis and Environmental Epidemiology, in which the authors reported on a study conducted to measure the total airborne fiber concentrations during the use of four asbestos-containing products: a coating, two mastics, and an adhesive (Paustenbach et al. 2004). These products contained 1-9 percent asbestos, with the adhesive containing 8-9 percent asbestos. In this study, the personal and area airborne concentrations of asbestos fibers released during five different activities (application, spill cleanup, sanding, removal, and sweep cleaning) were measured during periods of approximately 30 min to 8 hours depending on the activity. Total airborne fiber concentrations were measured using phase contrast microscopy (PCM), and asbestos-specific fiber counts were measured using transmission electron microscopy (TEM) to determine a PCME airborne asbestos concentration. Chrysotile asbestos fibers were detected by TEM in six of 452 samples, indicating that a very low percentage of fibers measured in the air were asbestiform. Task-based airborne chrysotile concentrations ranged from 0.003 to 0.04 fibers per cubic centimeter or ml (f/cc) (PCME by NIOSH 7402). These measurements were well below the current OSHA 8-hr TWA PEL of 0.1 f/cc. In their paper, the authors concluded that these results indicated that there was "virtually no occupational exposure to the asbestos in these products during the application, spill cleanup, cutting and removal, and sweep cleanup" (Paustenbach et al. 2004).

Airborne Fiber Concentration Measurement at General Dynamics in Mr. LaFrentz's Work Area

The exhibit to Mr. LaFrentz's testimony addressing the adhesive material tested contained a report with a single airborne fiber sample collected during Mr. LaFrentz's work at General Dynamics on February 26, 1980. According to the report, a one-minute sample was collected

during "belt sanding P 653 panels" (LaFrentz Plaintiff 2 Exhibit). The airborne fiber concentration over one minute was 28.8 f/cc; the analytical method was not reported, but appeared to be PCM. As noted by Paustenbach et al. (2004), a very small percentage of fibers measured during the manipulation of adhesives may be asbestiform, and therefore PCM concentrations alone may overestimate the asbestos-specific airborne fiber concentration measured using TEM or PCME.

It was noted in the report that during sampling, Mr. LaFrentz "wore a disposable respirator approved for use in asbestos contaminated atmosphere" and described the respirator as a "3M model 8710" (LaFrentz Plaintiff 2 Exhibit).

Summary: Mr. LaFrentz's Cumulative Asbestos Exposure Potential During Drilling Activities Involving Aircraft Test Panels

Any exposure that Mr. LaFrentz may have experienced as a result of working with these encapsulated products would have been well below the cumulative asbestos exposure potential associated with working at the current OSHA PEL for asbestos over 45 years, and also within or below the range of cumulative lifetime ambient or background exposures experienced by anyone in the general U.S. population.

Based on Equation 1 above, the following two parameters are necessary for estimating cumulative exposure potential: duration and frequency of exposure (E_D in years) and the airborne fiber concentration associated with the work performed (C_{8hr} in f/cc).

Summary: Duration and Frequency (E_D) of Exposure Potential to Mr. LaFrentz

Regarding Mr. LaFrentz's work with the honeycomb panels over approximately three years, Mr. LaFrentz described that he would work on a plastic bin of the panels that contained anywhere from 8 to 14 or 20 to 30 panels (LaFrentz Vol. I: p. 65; LaFrentz Vol. 2: p. 118-119). He described that he "might have to do this for two days" and then he "might... not have another bin come out for a month" (LaFrentz Vol. I: p. 65, l. 12-13). This frequency and duration of work is equivalent to 576 hours (8 hours/day x 2 days/month x 36 months). On an occupational year basis, this is equivalent to 0.28 occupational year (576 hours ÷ 2,080 hours/occupational year).

Based on the number of panels he described, and his testimony that he would typically drill either two or four holes per panel, this would approximately equate to an upper bound of approximately 90 holes drilled per plastic bin of panels. Regarding belt sanding specifically, this

might take 10-20 seconds per hole drilled to smooth out any burrs while not also degrading or altering the panel surface, or up to approximately 30 minutes per day (up to 20 sec. per hole drilled x up to 90 holes drilled ÷ 60 sec/min).

Summary: Measured Airborne Fiber Concentrations (C_{8hr}) during Work with Encapsulated Adhesive Products

For adhesives and similar products, Paustenbach et al. (2004) reported that airborne fiber concentration measurements were well below the current OSHA 8-hr TWA PEL of 0.1 f/cc, or between 0.003 f/cc and 0.04 f/cc. Additionally, a very small percentage of airborne fibers measured were asbestiform. The authors concluded that based on the measured results, there would be "virtually no occupational exposure to the asbestos in these products during the application, spill cleanup, cutting and removal, and sweep cleanup" (Paustenbach et al. 2004).

Based on the single sample collected at General Dynamics during Mr. LaFrentz's employment, if he had hypothetically spent as much as 30 minutes per day actively belt sanding panels (as calculated above), and if the airborne fiber concentration reported was representative of asbestos fibers specifically (for which there is no evidence), then the 8-hour TWA airborne fiber concentration during this work would be equivalent to 1.8 f/cc [(28.8 f/cc x 30 minutes) + (a midpoint of 0.02 f/cc during Paustenbach et al. adhesives work x 450 minutes) ÷ 480 min over 8 hours]. According to the sample report in LaFrentz Plaintiff 2 Exhibit, the allowable exposure to asbestos at the time of sample collection was 2 f/cc, indicating that 1.8 f/cc as an 8-hour TWA would have been within the allowable limits at the time of sample collection. Additionally, the use of a respirator would serve to further reduce this exposure potential. At an APF of 10, the user would experience at least a 90% reduction in airborne fiber exposure potential.

Summary: Mr. LaFrentz's Cumulative Exposure Potential (C)

As previously discussed, cumulative lifetime background exposures on a working lifetime basis are equivalent to 45 working years at the current OSHA 8-hour TWA PEL of 0.1 f/cc which equates to a working lifetime of 4.5 fiber/cc-years. Ambient or background cumulative lifetime asbestos exposures to individuals in the U.S. have also been measured and found to be in the range of 0.002 to 0.4 f/cc-year on an environmental year basis (or 0.0084 to 1.68 f/cc-year on an equivalent occupational cumulative exposure basis).

Based on the specific duration and frequency that Mr. LaFrentz described working with the honeycomb aircraft panels (approximately 0.28 occupational year), his work drilling panels at General Dynamics between 1979 and 1981 or 1982 would have resulted in a cumulative lifetime asbestos exposure potential that is well within the occupational-equivalent cumulative working lifetime exposure at the current OSHA PEL of 4.5 f/cc-year, and also well within the background or ambient cumulative asbestos exposures experienced by the general population in the U.S., if not below the limit of detection (see **Eq. 1**). If should be noted that this would be true whether the sampling data from General Dynamics or the sampling data from Paustenbach et al. (2004) is used to calculate cumulative exposure potential. According to the weight of evidence in the peer-reviewed literature, exposures to asbestos to the U.S. population across the wide range of measured and reported background airborne fiber concentrations have not been shown to be associated with a statistically-significant increased risk of asbestos related disease, including mesothelioma.

Additionally, using respiratory protection during this work with an APF of 10 (equivalent to an exposure reduction of 90%) for approximately three years would result in an even lower cumulative exposure, which would be even further within the range of cumulative lifetime background or ambient exposures, if not below the limit of detection.

Mr. LaFrentz's Descriptions of Work Around Insulation

He also recalled that "one year [he] worked as an apprentice steamfitter" and believed that this was the following summer after the construction site job (LaFrentz Vol. I: p. 35, l. 24-25; p. 36, l. 1-2; p. 38). During this employment, he stated that he "helped one guy" and recalled that they were "redoing piping in the basement of an unoccupied hospital" (LaFrentz Vol. I: p. 38, l. 9-10). He indicated that the work he did was consistent with an apprentice, and that he would "put goop on pipes and [screw] them in and all the old pipes out" (LaFrentz Vol. I: p. 38, l. 20-21). He did not recall if they took any insulation off of the piping systems they removed (LaFrentz Vol. I: p. 168). He agreed that "the whole area was always dusty" (LaFrentz Vol. I: p. 170). He did not recall whether he wore any type of dust mast while performing this work (LaFrentz Vol. I: p. 170).

Airborne Fiber Concentration Studies Associated with Insulation Work

Studies have reported that average short-term fiber concentrations associated with insulation work ranged between 1.0 f/cc and 8.4 f/cc in industrial and commercial settings, and 0.2 f/cc and 226 f/cc in maritime settings (Cooper et al. 1968; Harries 1971). Similarly, Balzer et al. (1972)

reported average short-term fiber concentrations during a simulation study in which pipe covering was manipulated via hand sawing, band sawing, and power sawing and indicated that airborne concentrations for personal samples ranged from 1.3 f/cc to 2,629.7 f/cc. In 1986, the U.S. EPA's Airborne Asbestos Health Assessment Update reported that historic asbestos exposures to shipyard and industrial insulation were estimated to be in the range of 3 to 6 f/cc (on a long-term average or full-shift basis) between 1968 and 1971 (Nicholson 1972; USEPA 1986a). Acknowledging that certain asbestos-containing insulation products may have contained nearly double the asbestos content in the years prior to 1968, the study suggested that average exposures of insulation workers in the U.S. could have ranged from 10 to 15 f/cc for insulators in commercial and industrial construction and 15 to 20 f/cc for insulators in marine construction (USEPA 1986a).

It is well documented that from the 1930s until the early 1960s, amosite was the predominant fiber type used in many military and industrial insulation applications in both the U.S. and Europe (Balzer et al. 1968; Cooper et al. 1968; Mangold 2003; Murphy et al. 1971; Rushworth 2005; Harries 1968). Beginning in the 1930s, the U.S. Navy started using amosite asbestos insulation, and the use of this insulation on pipes and equipment was widespread due to its low thermal conductivity, strength, light weight, and high temperature limit (Fleischer et al. 1946). According to U.S. Navy specifications, the composition of asbestos-containing insulation was approximately 57-95% amosite and 6-43% chrysotile (Rushworth 2005). Similarly, Balzer and Cooper reported the asbestos content of insulation generally to be variable, and stated that insulation could contain chrysotile, amosite, other materials, or a combination of fiber types (Balzer et al. 1968). Entities such as Johns Manville and Owens Corning manufactured many insulating products, including products such as Kaylo insulation and Johns Manville insulation, that historically contained amphibole asbestos, for a wide variety of uses (Johns-Manville 1973, 1950-1965; Owens Corning 2000; Helser 1984; Johns-Manville 1963).

In the mid-1960s, researchers first demonstrated through epidemiological studies that tradesmen who routinely handled or worked in the vicinity of others using amosite-containing insulation were at an increased risk of developing asbestos-related diseases (Selikoff et al. 1965b; Selikoff 1965). This was likely due, in part, to the substantial concentrations of airborne asbestos fibers generated while thermal insulation was sprayed, installed, repaired, or removed from various structures, equipment, and associated piping.

VI. CLOSING COMMENTS

I submit these comments and am prepared to support them in both deposition and/or courtroom testimony. I may supplement this report if additional information becomes available or I am asked to address other issues.

Respectfully,

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August 14, 2020
Date

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